Supreme Court, U.S.
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No. 09-

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA ex rel.
JAMES HOPPER and COLIN HUTTO,
Petitioners,

v.

SOLVAY PHARMACEUTICALS, INC. and
UNIMED PHARMACEUTICALS, INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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March 4, 2010

QUESTION PRESENTED

1. Whether Rule 9(b), Fed. R. Civ. P. requires the identification of a specific false claim in order to plead a violation of the False Claims Act, 31 U.S.C. § 3729(a)(2).

LIST OF PARTIES TO THE PROCEEDINGS

Petitioners James Hopper and Colin Hutto were the relators in the Florida district court proceedings and the appellants in the Eleventh Circuit proceedings.

Respondents Solvay Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc. were the defendants in the Florida district court proceedings and the appellees in the Eleventh Circuit proceedings.

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Petitioners James Hopper and Colin Hutto respectfully petition for a writ of certiorari to review the judgment in this case of the United States Court of Appeals for the Eleventh Circuit.

OPINIONS BELOW

The opinion of the Eleventh Circuit (Pet. App. at A-35) is reported at 588 F.3d 1318.

The report and recommendation of the magistrate judge (Pet. App. at A-3) is reported at 590 F. Supp. 2d 1352. The district court's adoption of the recommendation is found at Pet. App. at A-32.

JURISDICTION

The judgment of the Eleventh Circuit was entered on December 4, 2009. This Court has jurisdiction to review the judgment of the Eleventh Circuit pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Rule 9(b), Fed. R. Civ. P., provides:

> In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge,

> and other condition of mind of a person may be averred generally.

Pertinent provisions of the False Claims Act, 31 U.S.C. §§ 3729-3733, are at Pet. App. at A-2.

INTRODUCTION

There is substantial disarray among the lower courts regarding application of Rule 9(b)'s heightened-pleading mandate to False Claims Act complaints. This split was brought into sharp relief by recent holdings in the First, Fifth, and Seventh Circuits, which essentially agree that a complaint which does not allege "details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (Higginbotham, J.); *accord United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29, 31 (1st Cir. 2009) (*pet. for cert. pending*, No. 09-654); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (Easterbrook, C.J.) (it is not "essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit").

The line of Eleventh Circuit decisions which led to dismissal here present the prudential gulf's far shore. The magistrate judge recommended dismissal on the basis that "in qui tam actions like this one, a False Claims Act count must, in order to satisfy Rule 9(b)'s particularity requirement, allege a false claim that was actually submitted to the government." Pet. App. at A-19. The magistrate judge recognized that "the relators have provided detailed allegations of various schemes to promote Marinol's off-label use," but recommended dismissal on the basis that petitioners had not supported their allegations with "*facts concerning false claims actually submitted to the government* for reimbursement." *Id.* at A-23 (emphasis supplied). The district court adopted the magistrate judge's recommendation, and the Eleventh Circuit affirmed, hardening its longstanding position, first articulated in *United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), that identification of a claim is the "*sine qua non*" of a False Claims Act complaint.

The Sixth and Tenth Circuits have embraced the Eleventh Circuit's position. *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 518 (6th Cir. 2009), *quoting United States ex rel. Bledsoe v. Community Health Systems, Inc.* (*Bledsoe II*), 501 F.3d 493, 504 (6th Cir. 2007) ("'pleading an actual false claim

with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b).'"); *United States ex rel. Sikkenga v. Regence Blue Cross Blue Shield of Utah*, 472 F.3d 702, (10th Cir. 2006) (affirming Rule 9(b) dismissal because relator failed "to identify any specific claim made by [defendant] for administrative costs under its contract.").

These decisions imbue Rule 9(b) with an iron grasp which far exceeds its intended reach, and ignore longstanding authority that "Rule 9(b)'s ultimate meaning is context-specific." *Williams v. WMX Technologies, Inc.*, 112 F.3d 175, (5th Cir. 1997). This authority mirrors this Court's recent observation that review of a complaint on a motion to dismiss is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ashcroft v. Iqbal*, — U.S. —, —, 129 S. Ct. 1937, 1950 (2009). Rather than serving to "protect defendants from the harm that comes to their reputations or to their goodwill when they are charged with serious wrongdoing," *Segal v. Gordon*, 467 F.2d 602, 607 (2d Cir. 1972), these cases create an insurmountable hurdle for *qui tam* relators who, no matter how much they bring to the table regarding a government contractor's violations of the False Claims Act, do not see the bills. As Chief Judge Easterbrook, joined by

Judge Posner, noted in *Lusby*, "[s]ince a relator is unlikely to have those documents unless he works in the defendant's accounting department," the requirement that details of a specific claim must be pled "takes a big bite out of *qui tam* litigation." 570 F.3d at 854.

Indeed, the court of appeals in this case not only held that details of a specific allegedly-false claim must be pled even where, as here, the claims are submitted by third parties, but squarely "h[e]ld that under § 3729(a)(2), a plaintiff must *prove* that the government in fact paid a false claim." This holding is inconsistent with this Court's conclusion in *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, —, 128 S. Ct. 2123, 2129-30 (2008) that presentment of a claim is not an element of a cause of action under subsection (a)(2) (which permits liability to attach regardless whether a claim is actually submitted). It also puts an impossible pleading burden on petitioners.

Grubbs, *Lusby*, and *Duxbury* return Rule 9(b) to its intended place in the panoply of pleading rules, and by doing so highlight the error below. This Court's intervention to resolve the conflict, which causes the success or failure of many *qui tam* complaints to be decided based on venue alone, is especially appropriate in light of the Court's recent reaffirmation of the role of

inference in initial pleadings in *Iqbal*, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007), and *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319-21 (2007). While there has been furor around these cases, there is no question that their central focus is the principle that a plaintiff's factual allegations are construed in favor of all inferences they reasonably support. That did not happen here.

In the alternative, if the Court does not grant review at this time, it should hold this case for disposition in light of *Ortho Biotech Products L.P. v. United States ex rel. Duxbury*, No. 09-654, which presents the question regarding whether the First Circuit erred in holding that a complaint, which did not identify a specific false claim, satisfied Rule 9(b).

STATEMENT OF THE CASE

This case revolves around the marketing of the synthetic marijuana drug Marinol by respondents. Marinol was approved by the Food and Drug Administration ("FDA") in 1985 for the narrow indications of persistent nausea in chemotherapy patients who do not respond to conventional treatment, and in 1991, for anorexia in patients with full-blown AIDS.

Marinol was not very effective at treating the first condition, and never garnered much use. To the extent Marinol helped AIDS patients, the market shrank as treatments to prevent HIV from becoming AIDS gained traction.

Faced with the obsolescence of its product, Respondent Solvay conceived the strategy of flipping the two approved uses, marketing Marinol for appetite loss in cancer patients ("cancer cechexia") and nausea caused by highly-active antiretroviral drug therapy ("HAART") in people who were HIV-positive. Respondents capitalized on the seeming similarity of these conditions to those approved by the FDA. They are, however, dramatically different. App. Pet. at A-64, ¶ 3. The use of Marinol to treat these conditions is not just outside the FDA approval, but wholly without scientific basis. *Id.* at A-65, ¶ 4.

Not content with these new horizons, respondents also decided to market Marinol as an appetite stimulant in nursing-home patients. This gambit was especially sinister, because the FDA specifically warned against the use of Marinol in patients prone to disorientation or dementia because of the mood-altering tendencies of the drug. *Id.* at A-79, ¶¶ 42-43.

Both petitioners were sales representatives for Solvay, and Mr. Hopper worked as a sales trainer, charged with translating policy into practice. Petioners' job was to implement respondents' marketing plans for Marinol in and around Birmingham, Alabama. They filed this case in the Middle District of Florida on November 22, 2004, alleging that respondents violated the False Claims Act by causing submission of Medicaid claims through promotion of Marinol for purposes which the Food and Drug Administration did not approve.

The United States was actively investigating the case when, on October 27, 2006, the district court unsealed the case after the United States indicated that it was "not prepared to intervene at this time" because its investigation was incomplete. Once the complaint was unsealed and served, relators filed a second amended complaint, which the district court dismissed on defendants' motion.

On appeal, petitioners asserted that the complaint set forth in complete detail the defendants' illegal marketing scheme, and showed that as that scheme took hold, sales of Marinol skyrocketed. Petitioners argued that the complaint included ample indicia of reliability, as seemingly required by *Clausen v. Laboratory Corp. of America*, 290 F.3d at 1311; and

second, that this Court's recognition in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321-22 (2007) that plaintiffs need only raise facts demonstrating a "strong inference" of liability in meeting heightened pleading burdens, could not be reconciled with the mandate that specific evidence be pled.

The court of appeals rejected these arguments and affirmed dismissal.

REASONS FOR GRANTING THE PETITION

Each time this Court has granted *certiorari* relating to the proper interpretation of Rule 9(b)'s particularity requirement, the result has been the curbing of application of the Rule beyond its stated purpose. In *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002), Justice Thomas wrote for a unanimous Court rejecting application of Rule 9(b) to Title VII cases. In *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit,* 507 U.S. 163, 168 (1993), Chief Justice Rehnquist wrote for a unanimous Court rejecting the application of Rule 9(b) to cases seeking to impose liability on municipalities for civil rights violations. One commentator has referred to this Court's Rule 9(b) cases as "explicit Supreme Court

direction to stop" using the rule inappropriately.[1]

It is particularly appropriate for the Court to consider the proper application of Rule 9(b) to False Claims Act cases in light of its re-examination of long-standing rules of pleading in *Iqbal* and *Twombly*, and its enunciation of the "strong inference" heightened pleading standard under the Private Securities Litigation Reform Act in *Tellabs*, 551 U.S. at 328.

A. This Court Should Grant Certiorari to Decide Whether a *Qui Tam* Complaint Can Satisfy Rule 9(b) Without Pleading Evidence of a Specific Claim for Payment.

The justification for the dismissal of petitioners' complaint under Rule 9(b) is the uneven line of Eleventh Circuit cases holding that it is impossible to infer the existence of a claim for payment from the circumstances alleged by relators.[2] And these cases, in

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[1] Fairman, Christopher M., *An Invitation to the Rule-makers—Strike Rule 9(b)*, 38 U.C. Davis L. Rev. 281, 307 (2004).

[2] *Compare United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003) (court cannot infer claim); *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005), *cert. denied*, 549 U.S. 810 (2006) (same); *United States ex rel. Atkins v. McInteer*, 470

turn, are predicated on the assertion that "presentment of a false claim is the *sine qua non* of a False Claims Act violation without which 'there is simply no actionable damage to the public fisc.'" *Grubbs*, 565 F.3d at 186, *quoting Clausen*, 290 F.3d at 1311.

This statement of "essential elements" is wrong on both counts. First, the Second Amended Complaint alleged that respondents violated the False Claims Act by intending to *cause* the submission of false claims *by others*, in violation of 31 U.S.C. § 3729(a)(2)—which permits liability to attach regardless whether a claim is actually submitted. *Allison*, 553 U.S. at —, 128 S.Ct. at 2129-30. Second, there is no damage element in a case under the False Claims Act. *E.g. Grubbs*, 565 F.3d at 189 n.28; *accord* Rex Trailer Co. v. United States, 350 U.S. 148, 153 n.5 (1956); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (affirming

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F.3d 1350 (11th Cir. 2007) (same); *United States ex rel. Sanchez v. Lymphatx, Inc.*, — F.3d —, 2010 U.S. App. LEXIS 3174 at *5-6 (11th Cir., Feb. 18, 2010) (same), *with United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005) (Rule 9(b) satisfied when relator alleges personal knowledge of false claims). In *Sanchez*, however, the court expressed doubt about the vitality of *Walker* in light of the prior panel rule. 2010 U.S. App. LEXIS 3174 at * 5 n.4.

without discussing the district court's conclusion that the United States could recover under the False Claims Act despite the absence of any actual damages).

Indeed, the requirement that relators must identify specific claims is all but impossible where, as here, third parties—not respondents—were the parties actually submitting the claims for payment. This point is squarely made in *Duxbury*. In rejecting the argument that Rule 9(b) requires relators to identify specific false claims, the court wrote:

> This was error. In *Rost*, we noted a distinction between a *qui tam* action alleging that the defendant made false claims to the government, and a *qui tam* action alleging that the defendant induced *third parties* to file false claims with the government . . . In the latter context, we held that a relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility['.]'

579 F.3d at 29, *quoting U.S. ex rel. Rost v. Pfizer*, 507 F.3d 720, 733 (1st Cir. 2007) and *citing Grubbs*, 565 F.3d at 190. These holdings make good sense, because where the scheme is to cause a third party to make false claims, the claim itself cannot be one of the "circumstances of the fraud" under Rule 9(b).

Respondents in this case are not alleged ever to have submitted a claim for payment to Medicaid. Rather, they are alleged to have disseminated falsehoods to physicians about Marinol, inducing them to write prescriptions to patients who took those prescriptions to pharmacists who then obtained reimbursement from public sources.[3]

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[3] The court of appeals asserted that petitioners "failed to allege that the defendants intended for the government to rely on their false statements in deciding whether to pay a false claim." Pet. App. at A-59, *citing Allison Engine*, 553 U.S. at —, 128 S. Ct. at 2128. Rule 9(b), of course, specifically excludes state of mind from its ambit. While it is true that the Second Amended Complaint, which was filed well before this Court's decision in *Allison*, does not incant this exact phrase, petitioners repeatedly and squarely allege that respondents "affirmatively predicated their off-label marketing plan on their knowledge that false claims for off-label uses would be submitted and would be reimbursed," (Pet. App. at A-131, ¶ 234) and that:

> Solvay was aware that its illegal promotion did in fact result in false claims to Medicaid and other government payors for the off-label use. Solvay was aware that its promotion activities were a substantial causal factor in producing the claim.

Id. at A-136, ¶ 242. The Eleventh Circuit found this insufficient, instead citing that failure to also allege the government's actual knowledge of the illegal marketing campaign prevented the conclusion that Solvay intended for that campaign to influence the government's decision to pay. *Id* at A-60. Petitioners respectfully assert that the allegations of the Second Amended Complaint amply plead that Solvay intended to get false claims paid or

Additionally, the Eleventh Circuit's cases and their progeny ignore the role of inference in the pleading of lawsuits - a role central to this Court's recent cases resetting the contours of pleading practice, as well as last year's First, Fifth, and Seventh Circuit's 9(b) holdings.

In *Lusby*, the district court refused to infer from the fact that parts were improperly inspected and then shipped to the United States that a claim was made which included a certificate of conformance. In finding error, the Seventh Circuit observed:

> [M]uch knowledge is inferential—people are convicted beyond a reasonable doubt of conspiracy without a written contract to commit a future crime—and the inference that *Lusby* proposes is a plausible one.

570 F.3d at 854. Similarly, in *Grubbs*, the district court refused to allow the inference that claims were submitted. In reversing the decision of the district court, Judge Higginbotham wrote:

> If at trial a *qui tam* plaintiff proves the

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approved by Medicaid.

> existence of a billing scheme and offers particular and reliable indicia that false bills were actually submitted as a result of the scheme . . . a reasonable jury could infer that more likely than not the defendant presented a false bill to the government, this despite no evidence of the particular contents of the misrepresentation.

565 F.3d at 189-90.

In fact, there are few, or perhaps no, things which cannot be found by a trier of fact to be true on the basis of inference. This Court said as much in *U.S. Postal Serv. Bd. of Governors v. Aikens*, 460 U.S. 711, 714 n.3 (1983): "As in any lawsuit, the plaintiff may prove his case by direct or circumstantial evidence." And in *Tellabs*, the Court emphasized that "under this Court's construction of the 'strong inference' standard, a plaintiff is not forced to plead more than she would be required to prove at trial." 551 U.S. at 328.

This Court's recent analysis of pleading standards underscores its commitment to preserving the ability of plaintiffs to rely upon legitimate inferences. In *Twombly*, the Court reached its decision based on reaffirming the longstanding principle that courts deciding whether to dismiss a complaint, must assume all the allegations in the complaint are true

and give the plaintiff the benefit of all plausible inferences derived from the facts alleged. 550 U.S. at 555-56.

Also, as Justice Souter noted for a unanimous Court in *Rotella v. Wood*, 528 U.S. 549, 560 (2000), Fed. R. Civ. P. 11(b)(3) "allow[s] pleadings based on evidence reasonably anticipated after further investigation or discovery."

The decision below sweeps these principles aside, refusing to allow *any* inferences despite the fact that petitioners allege that as respondents' illegal marketing campaign gained steam, Medicaid reimbursements for Marinol more than tripled: Medicaid paid $64 million for Marinol during the eight years before the off-label marketing commenced, and paid $167 million for Marinol in the four years after the illegal conduct began. Pet. App. at A-84, ¶ 57, A-132, ¶ 237.

The complaint also identified 13 oncologists who respondents targeted for off-label marketing activities. Pet. App. at A-137, ¶ 245. None wrote any prescriptions for Marinol in 2000, before the marketing campaign began. *Id.* As the off-label campaign took hold, their prescribing increased in proportion to the intensification of the marketing effort. The group

wrote 29 Marinol prescriptions in 2001; 103 in 2002; 134 in 2003; and 142 in 2004. *Id.* Solvay specifically targeted each for illegal marketing, providing petitioner Hopper with data purchased by Solvay which showed the doctors' prescribing patterns for both Marinol and its principal competitor.

The complaint also demonstrates that prescriptions for Marinol increased dramatically once the off-label campaign began. Petitioners allege:

- Among the 120 physicians who wrote the most prescriptions for Marinol during the period 2000-2004, 58 (49%) were oncologists. Pet. App. at A-85, ¶ 61. Only 14 (24%) of these 58 oncologists wrote any prescriptions for Marinol in 2000, and of those 14, six (11%) wrote three or fewer prescriptions. (*Id.*) Those 58 oncologists wrote a total of 88 Marinol prescriptions in 2000—an average of 1.5 apiece. *Id.*

- In 2001, after the off-label campaign took hold, the 58 oncologists wrote 765 prescriptions—an 869% increase from 2000 (*Id.* at A-86, ¶ 62) and an average of 13.2 apiece.

- The 58 oncologists wrote 1,278 Marinol prescriptions in 2002, 167% of the 2001 figure and a 14-fold increase compared to 2000. *Id.* at A-99, ¶ 115.

The complaint also shows an exponential increase in the total number of prescriptions written for Marinol as the off-label campaign took hold:

- In 2000, before the off-label campaign began, 10,367 prescriptions were written for Marinol. In 2001, almost 17,000: A 62% increase. *Id* at A-138, ¶ 249.

- In 2002, almost 65,000 prescriptions: An increase of almost 300% year over year, and a 526% increase from 2000. *Id.*

- In 2003, 139,615 prescriptions: A 115% increase over 2002, and a 1,250% increase over 2000. *Id.*

Petitioners also allege that respondents focused closely on the availability of Medicaid reimbursement for Marinol, predicating the illegal marketing campaign on its availability, projecting that 30% of sales would be to Medicaid patients, and closely tracking Medicaid sales. Pet. App. at A-131, ¶¶

234-235.

Neither the district court nor the court of appeals suggested that these facts did not support a compelling inference that the illegal marketing campaign drove the increase in Medicaid reimbursements. Rather, both held that *inferences with respect to identification of false claims were not permitted by Rule 9(b) at all.* This holding was in error.

B. There is a Clear Circuit Split Regarding the Application of Rule 9(b) to *Qui Tam* Complaints, With the First, Fifth, and Seventh Circuits Squarely Rejecting the Rule Applied Here.

In the past year, three well-reasoned decisions from different circuits—*Grubbs*, *Lusby*, and *Duxbury*—have squarely repudiated the reasoning which was utilized by the courts below.

Grubbs articulates a clear Rule 9(b) standard consistent with this Court's recent cases and the realities of the False Claims Act:

> [T]o plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a

> relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

565 F.3d at 190.

However, because *Grubbs* dealt only with claims brought under (a)(1), the Court should clarify that with respect to claims under (a)(2) where no claim is required to establish liability and, in a case such as this where all claims are filed by third parties, that Rule 9(b) is satisfied by alleging particular details of a scheme to cause the submission of false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

This is the essence of *Duxbury*, a case similar to this. The First Circuit's treatment of the (a)(2) issue. *Duxbury* and *Rost* establish a fully-appropriate Rule 9(b) standard for such cases: "[A] relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim." *Duxbury*, 579 F.3d at 29, *quoting Rost*, 507 F.3d at 733 .

C. The Eleventh Circuit's Application of Rule 9(b) in *Qui Tam* Cases is Inconsistent with This Court's Decisions in *Iqbal, Tellabs*, and *Twombly*.

The holdings below are not merely inconsistent with cases from other circuits. They are also inconsistent with this Court's recent reshuffling of the pleading deck.

In *Tellabs*, the Court, in evaluating a heightened-pleading standard, held that factual allegations in complaints must be taken as true and that the complaint "in its entirety" must be considered in determining whether, *on the facts alleged*, a strong inference of fraud can be reached. 551 U.S. at 322-23, 127 S. Ct. at 2509.

Here, there is no question that petitioners set out the scheme to cause submission of false claims in ample detail, and that the trial court found as much. However, the court of appeals made clear that without specific fact pleading of a claim, a False Claims Act complaint will fail. There is no support for this result in this Court's cases, and *Tellabs* makes clear that even where heightened pleading rules apply, *all* allegations must be considered. The inquiry, in short, must focus

on what is pled, rather than what is *not* pled.

The ruling below is equally inconsistent with the holdings in *Iqbal* and *Twombly*, both of which highlight the importance of taking a complaint's allegations as true, *and* affording the plaintiff the benefit of all reasonable inferences drawn therefrom. *Iqbal*, 129 S. Ct. at 1940; *Twombly*, 550 U.S. at 555-56.

D. The Court Should Hold This Case for Disposition in Light of *Duxbury*, No. 09-654, Which Presents the Question, in a Case Similar to This One, Whether the First Circuit Erred in Holding That a Complaint Which Did Not Identify a Specific False Claim Satisfied Rule 9(b).

The second question presented in *Duxbury* is:

> Whether an FCA relator, alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) of the Federal Rules of Civil Procedure without identifying a single false or fraudulent claim, but merely by alleging facts sufficient 'to strengthen the inference of fraud beyond possibility.'

Petition for Certiorari at I. The Court has asked for

the views of the Solicitor General on the questions presented in *Duxbury*.

While the issues presented in this case are worthy of this Court's review, if it is not inclined to grant the petition, petitioners ask that the Court defer disposition of this matter pending resolution of *Duxbury*.

CONCLUSION

The Petition for a writ of certiorari should be granted.

Respectfully submitted,

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Second Amended Complaint A-63

FALSE CLAIMS ACT

Section 3729, subsections (a)(1 and (a)(2), of Title 31 of the United States Code provides:

31 U.S.C. § 3729

(a) Liability for certain acts. Any person who—

> **(1)** knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> **(2)** knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government . . .

is liable to the United States Government for a civil penalty of not less than $ 5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF MASSACHUSETTS, STATE OF ILLINOIS, ex rel. JAMES HOPPER and COLIN HUTTO,

Plaintiffs and Relators,

v.

SOLVAY PHARMACEUTICALS, INC., et al.,

Defendants.

CASE NO: 8:04-cv-02356-T-23TGW

REPORT AND RECOMMENDATION

Qui tam relators allege violations of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and several analogous state statutes, arising from the defendants' alleged illegal marketing of the prescription drug Marinol for uses not approved by the U.S. Food and Drug Administration ("FDA"). They contend that the

defendants' marketing campaign caused physicians to prescribe Marinol for off-label uses to government healthcare beneficiaries, which resulted in the submission of false or fraudulent claims to the government for reimbursement of Marinol's cost. The defendants have moved to dismiss the second amended complaint on the ground that the relators failed to plead the submission of specific false claims to the government with the particularity required by Rule 9(b), F.R.Civ.P. (Doc. 88). The law of the Eleventh Circuit clearly holds that, in the circumstances presented here, the failure to allege the actual submission of a specific false claim is fatal. I therefore recommend that the motion to dismiss be granted.

I.

Relator James Hopper worked as a sales representative for defendant Solvay Pharmaceutical, Inc.'s Mental Health Division from 1999 until December 2005 (Doc. 84, ¶ 14).[1] Relator Colin Hutto was a sales representative for Solvay from 1999 until late 2003 (*id.*, ¶ 15). Hopper and Hutto allege that, as sales representatives, they were required to implement an illegal marketing plan for the

[1] During 2002, Hopper was a Solvay district sales trainer (Doc. 84, ¶14).

prescription drug Marinol, which is distributed by Solvay (*id.*, ¶¶ 14, 15).[2]

Marinol is a synthetic form of delta-9-tetrahydrocannbinol ("THC"), which is the major active component of marijuana (*id.*, ¶36). The FDA first approved Marinol in 1985 for the treatment of "nausea and vomiting associated with cancer in chemotherapy patients who have failed to respond adequately to conventional antiemetic treatments" (*id*, ¶38). In 1991 the FDA also approved Marinol for anorexia associated with weight loss in patients with AIDS (*id*, ¶39).

The relators claim that, through the 1990s, the market for Marinol was small because it was not generally viewed as a useful product for its on-label use (*id*, ¶¶ 57-60). Consequently, despite Marinol's limited approval as an appetite stimulant in certain AIDS patients, Solvay allegedly developed in 2001 an aggressive off-label marketing campaign for Marinol, promoting it to physicians as an appetite

[2] Defendant Unimed Pharmaceuticals, Inc. has held the FDA drug application for Marinol since 1985 (Doc. 84, ¶41). Unimed was acquired by Solvay in July 1999 and is its wholly-owned subsidiary (*id.*, ¶18). Since 2001, Marinol has been marketed and distributed exclusively by Solvay (*id.*, ¶58).

stimulant in patients with appetite loss due to a variety of conditions, including cancer and aging (*id.*, ¶¶ 62, 64. 65). It also allegedly marketed Marinol as a drug that could collectively treat appetite, nausea, and mood in cancer and HIV/AIDS patients (*id.*, ¶¶ 84, 117, 139).

The FDA regulates the sales and marketing activities of pharmaceutical manufacturers in the United States (*id.*, ¶21). After the FDA approves a drug for a particular use, it does not regulate how the drug is prescribed (*id.*). Thus, a physician may lawfully prescribe a drug to a patient for a use other than that for which it was approved by the FDA, and this is known as "off-label" use (*id.*).

However, the FDA prohibits a drug manufacturer from marketing or promoting a drug for non-approved use (*id.*, ¶23). For example, a drug manufacturer may not initiate discussions with, or disseminate materials to, a medical professional regarding off-label use of a drug (*id.*, ¶¶ 23, 24, 31, 32). Furthermore, federal healthcare programs, including Medicaid and Medicare, do not knowingly pay for medications that are not prescribed for a medically acceptable indication, or that are prescribed as a result of false or misleading information provided by

the drug manufacturer (*id.*, ¶¶ 34, 35).[3] In addition, the federal programs do not pay for drugs that were prescribed as a result of unlawful inducements or unlawful marketing activities by the manufacturer (*id.*).

The relators allege that Solvay spent millions of dollars to train its sales representatives, and educate health care providers, about the use of Marinol for off-label purposes (*see, e.g., id.*, ¶¶ 113, 114, 125, 126, 131, 140-43, 169, 170, 179, 190, 222-28). Further, the relators allege that a Solvay sales representative arranged for lunches, ice cream, and Starbucks coffee to be brought to the offices of specifically targeted physicians in order to induce physicians to prescribe Marinol for off-label uses (*id.*, ¶¶ 107, 108). The relators, moreover, allege that the defendants paid physicians for preceptorships, and attendance at meetings and events, which were intended to induce the physicians to prescribe Marinol

[3] The federal government pays prescription drug benefits under a variety of health care programs, including Medicare, Medicaid, CHAMPUS/Tricare, the Veteran's Health Administration, Federal Employees Health Benefits Program, and the Indian Health Bureau (*id.*, ¶34).

for off-label uses (*id.*, ¶¶ 193-221).[4]

After the implementation of the alleged illegal marketing program, the number of prescriptions for Marinol increased substantially, from 10,367 in 2000 to 124,208 in 2004 (*id.*, ¶249). Concomitantly, payment for Marinol by public funding sources, such as Medicaid, increased (*id.*, ¶95). Thus, Medicaid payments for Marinol during the years of the illegal off-label marketing campaigns increased from about $ 15 million in 1999 to over $ 69 million in 2005 (*id.*, ¶237).

The relators allege that the majority of the Medicaid claims for Marinol were made as a result of prescriptions written for off-label uses that were not medically indicated or necessary, and the issuance of which were influenced by the defendants' alleged illegal marketing campaign (*see id.*, ¶¶ 238-44). Therefore, they allege that, when claims were submitted to the government for reimbursement of the cost of Marinol, they were false because these off-label uses were not eligible for federal financial participation or covered by state Medicaid programs

[4] During a preceptorship, a sales representative is allowed to "shadow" a physician ostensibly to learn about the physician's medical practices (*see* Doc. 84, ¶195).

(*id.*, ¶¶ 239, 241).[5]

On November 22, 2004, the relators filed a complaint under seal against the defendants pursuant to the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. 3729, *et seq.*, alleging that the illegal marketing campaign caused the filing of false claims for reimbursement of the cost of Marinol (Doc. 3). The United States was served with the complaint and commenced its investigation of the allegations (*see* Doc. 5). It sought, and received, several extensions of time to notify the court whether it would intervene in the case (Docs. 5, 7, 13, 14, 17, 18). During its investigation, Solvay produced to the government hundreds of thousands of documents pursuant to government subpoenas (*see* Doc. 89-2).

The relators filed their fust amended

[5] Pursuant to the Medicaid program, the federal government pays to states a portion of medical expenses incurred for health care provided to low-income individuals (Doc. 84. ¶230). The states submit quarterly Medicaid Statements of Expenditures to the federal government and they receive some reimbursement from the federal government for drugs that have been prescribed for a medically acceptable use (*id.*, ¶¶ 230-32). The relators contend that the defendant's alleged illegal marketing activities also resulted in false claims to Medicare and other government health care programs (*see id.*, ¶¶ 260-69).

complaint on July 7, 2005 (Doc. 11). In July 2006, the United States requested a fourth six-month extension of time in which to decide whether to intervene in the case, but the court ordered the United States to decide whether it would intervene by October 27, 2006 (Docs. 21, 24). On that date, the United States notified the court that it was "not able to decide by the Court's deadline whether to proceed with the action" and it was therefore "not intervening at this time" (Doc. 25).

On November 17, 2006, the court ordered this lawsuit unsealed (Doc. 28). The relators subsequently moved to file a second amended complaint (Doc. 65), and the motion was granted (Doc. 83). The second amended complaint alleges violations of the FCA and analogous Illinois, California, and Massachusetts state statutes (Doc. 84, pp. 61-73).

The relators state in the second amended complaint that the "gravamen of [their] claims is that the Defendants developed and successfully executed a sophisticated marketing plan with the purpose of inducing physicians to prescribe the prescription drug Marinol ... for uses which are neither FDA approved nor demonstrated to be safe and effective" (*id.*, p. 2, ¶3). The relators allege further that the defendants' conduct "has caused submission for reimbursement by Government Healthcare Programs of millions of

dollars worth of prescriptions which were ineligible for such reimbursement" (*id.*, ¶4). The second amended complaint also alleges kickbacks to physicians and other healthcare providers, such as remuneration under the guises of preceptorships, speaker programs, gifts, free entertainment and food, in order to induce them to prescribe Marinol for off-label appetite stimulation (*id.*, p. 3, ¶¶ 7, 8).

The defendants have filed a motion to dismiss the second amended complaint pursuant to Rules 9(b), and 12(b)(1), (6), F.R.Civ.P. (Doc. 88). They allege that the relators have failed to plead their allegations of fraud with particularity, as required by Rule 9(b), F.R.Civ.P. (*id.*). Further, the defendants argue that the court lacks subject matter jurisdiction over the second amended complaint because some of its allegations are based on publicly disclosed information for which the relators are not the original source of the information (*id.*).

The relators filed a memorandum in opposition to this motion, arguing that their allegations of fraud satisfy Rule 9(b)'s particularity requirement (Doc. 92). The relators also dispute the defendants' challenge to subject matter jurisdiction, contending that the allegations in the second complaint are not based upon publicly disclosed

information and that they were the original sources of that information (*id.*). The defendants, with leave of court, filed a reply (Doc. 97).

The motion was referred to me for disposition, if it was to be denied, and for a report and recommendation, if the case was to be dismissed (Doc. 98). Oral argument was subsequently conducted on the motion (Doc. 100).

II.

As indicated, the relators' second amended complaint alleges violations of two provisions of the FCA (*see* Doc. 84, ¶273). Pursuant to 31 U.S.C. 3729(a), civil liability arises when a person:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or

approved by the Government[.][6]

. . .

Statutory sanctions for FCA violations include civil penalties and treble damages. 31 U.S.C. 3729(a).

To assist the government in uncovering fraud, the FCA authorizes *qui tam* actions, in which a private citizen, or "relator," brings a lawsuit for violations of the FCA on behalf of the United States government. 31 U.S.C. 3730(b). After filing a complaint *in camera*, the relator provides the federal government with a copy of the complaint and a written disclosure of substantially all material evidence and information possessed by the relator. 31 U.S.C. 3730(b)(2).[7] The government has sixty days to intervene in the case. *Id.* If the government elects not

[6] For purposes of the FCA, a "'claim' includes any request or demand ... for money ... which is made to a contractor, grantee or other recipient if the United States Government provides any portion of the money ... which is requested or demanded, or if the Government will reimburse such contractor, grantee or other recipient for any portion of the money ... which is requested or demanded." 31 U.S.C. 3729(c).

[7] Pursuant to §3730(b)(2), the relator's complaint is filed *in camera*, and remains under seal for at least sixty days and is not served upon the defendant until the court so orders.

to proceed with the action, the relator has the right to conduct the lawsuit. 31 U.S.C. 3730(c)(3).

The relator stands to gain significantly from bringing a *qui tam* action. Thus, where, as here, the government does not assert its statutory right to take over the case from the relators, they can recover between twenty-five and thirty percent of any monies recovered from a settlement or judgment, plus reasonable expenses and reasonable attorneys' fees and costs. 31 U.S.C. 3730(d)(2).

III.

A. The defendants have asserted, as a secondary argument, that this lawsuit must be dismissed for lack of subject matter jurisdiction. *See* Rule 12(b)(1), F.R.Civ.P. Although the defendants did not press this argument at the hearing, the suggestion that subject matter jurisdiction is absent must be addressed first because if "the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Rule 12(h)(3), F.R.Civ.P.; *see also U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1356 n. 10 (11th Cir. 2006)("A district court must examine its subject matter jurisdiction even though the parties do not challenge it.").

The defendants contend that the FCA bars jurisdiction over the second amended complaint because it purportedly contains allegations from publicly disclosed documents, and the relators were not the original source of that information (Doc. 88, pp. 29-40). In this regard, the FCA provides (31 U.S.C. 3730(e)(4)):

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action

> under this section which is based on the information.

The purpose of this jurisdictional bar is to prevent opportunistic lawsuits by individuals with no personal knowledge of fraud who gathered their information from the public domain. *See Cooper v. Blue Cross and Blue Shield of Florida, Inc.*, 19 F.3d 562, 565 (11th Cir. 1994).

It is the relators' burden to establish subject matter jurisdiction. *See McElmurray v. Consolidated Gov't of Augusta-Richmond Cty.*, 501 F.3d 1244, 1251 (11th Cir. 2007). A motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), F.R.Civ.P., can be based upon either a facial or a factual challenge to the complaint. *Id.* If the challenge is facial, the court considers the allegations in the plaintiff's complaint as true. *Id.* Factual attacks challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such as testimony and affidavits, are considered. *Id.* In the event of a factual challenge, "the district court must give the plaintiff an opportunity for discovery and for a hearing that is appropriate to the nature of the motion to dismiss." *Williamson v. Tucker*, 645 F.2d 404, 414 (5th Cir. 1981), *cert. denied*, 454 U.S. 897, 102 S. Ct. 396, 70 L. Ed. 2d

212 (1981).

A facial challenge clearly fails in this case. The relators have specifically alleged that "[n]one of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. 3730(e)(4), and Relators are an original source of the facts alleged in this Complaint" (Doc. 84, ¶16). This allegation defeats a contention that the second amended complaint, on its face, shows that §3730(e)(4) forecloses subject matter jurisdiction.

Further, a factual challenge is premature, particularly since no discovery has been conducted in this case. A factual challenge, moreover, raises the unsettled question of whether production of documents pursuant to a Department of Justice subpoena and the subsequent sharing of those documents with the relators constitutes a public disclosure under §3730(e)(4). *Compare U.S. ex rel. Fowler v. Caremark Rx. L.L.C.*, 496 F.3d 730, 736-37 (7th Cir. 2007), *cert. denied*, 128 S. Ct. 1246, 170 L. Ed. 2d 66 (2008) (public disclosure); *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 728 (1st Cir. 2007) (no public disclosure). There is no justification for proceeding toward a difficult and burdensome factual challenge when the Rule 12(b)(6) contention is easily resolved and disposes of the case.

B. The defendants' primary argument is that the second amended complaint should be dismissed for failure to plead with particularity the contention that the defendants' alleged illegal marketing campaign caused the submission of false or fraudulent claims to the government (Docs. 88, 97). This contention is predicated upon Rule 9(b), F.R.Civ.P., which requires a party alleging fraud to "state with particularity the circumstances constituting fraud."

The relators have alleged that the "[d]efendants, through their illegal off-label marketing campaigns, knowingly caused the submission of hundreds of thousands of false ... claims" for off-label Marinol prescriptions, which resulted in the government's improper reimbursement of millions of dollars (Doc. 84, ¶¶ 4, 250, 275). The defendants argue that Eleventh Circuit caselaw requires that such a count must include specific allegations of an actual false claim that was submitted to the government (Doc. 88, p. 13). The defendants argue that the relators have instead asked the court to infer the existence of an actual false claim. In this respect, the defendants say that "[t]he [second amended complaint] points to no actual off-label prescription resulting from the alleged off-label marketing campaign, when or where such a prescription would have been written, or for

which patient" (*id.*, p. 7). They add that the second amended complaint does not identify "any alleged false claim actually submitted for reimbursement, ... let alone who submitted such a claim, when the claim was submitted ... [or] the content of the claim" (*id.*, p. 20) (emphasis omitted).

The relators concede that they have no evidence of a false claim. Rather, they argued at the hearing that the Eleventh Circuit's pleading requirements are not as limiting as the defendants suggest (*see also* Doc. 92, p. 12, n.14). Specifically, they contend that the Eleventh Circuit's requirement that allegations of false or fraudulent claims be supported by "indicia of reliability" is satisfied by allegations in the second amended complaint from which it can be inferred that a false claim was submitted to the government.

That is not the law of the Eleventh Circuit. There are three binding decisions, as well as an unpublished decision, that hold that, in *qui tam* actions like this one, a False Claims Act count must, in order to satisfy Rule 9(b)'s particularity requirement, allege a false claim that was actually submitted to the government. *U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105, 123 S. Ct. 870, 154 L. Ed. 2d 774

(2003): *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005), *cert. denied*, 549 U.S. 810, 127 S. Ct. 42, 166 L. Ed. 2d 18 (2006); *U.S. ex rel. Atkins v. McInteer*, *supra*. 470 F.3d 1350; *Mitchell v. Beverly Enterprises, Inc.*, 248 Fed. Appx. 73, 2007 WL 2551404 (11th Cir. 2007)(unpub. dec.), *reh'g en banc denied*, 255 Fed. Appx. 504 (11th Cir. 2007).

In *Clausen*, the *qui tam* relator, who worked in the medical testing industry and was a competitor of the defendant, alleged that the defendant was billing the government for unnecessary laboratory tests for patients who participated in government-funded health insurance programs. 290 F.3d at 1303. He identified patients allegedly subjected to improper testing, set forth the improper tests, and stated the dates on which those procedures were performed. *Id.* at 1304-05.

Although the relator in *Clausen* described in detail the defendant's alleged scheme to defraud the government, the Eleventh Circuit affirmed the dismissal of the complaint for failure to plead fraud with specificity because it did not contain "any billing information to support [the plaintiff's] allegation that actual false claims were submitted for payment." *Id.* at 1306. The Eleventh Circuit explained that the relator did not include a copy of a single actual bill or claim,

he did not identify the amounts of any charges or dates of claims, and he did not provide a single completed reimbursement form, *Id.* In sum, the relator in *Clausen* "failed to provide any ... information linking the testing schemes to the submission of any actual claims or any actual charges." 290 F.3d at 1313.

The Eleventh Circuit followed *Clausen* in *Corsello v. Lincare, supra.* In that *qui tam* suit, the relator, who had been a salesman for two of the defendants, alleged that the defendants had "engaged in various fraudulent schemes, including paying illegal kickbacks to physicians to induce referrals, falsifying certificates of medical necessity to provide unnecessary treatment, and billing for unnecessary or non-existent treatment to obtain Medicare payments unlawfully." 428 F.3d at 1011. A dismissal of the second amended complaint was upheld on appeal because the pleading "failed to allege when, where, and what violations of the False Claims Act occurred." *Id.* at 1013.

The Eleventh Circuit in *Corsello* said that, in order "[t]o state a claim under the False Claims Act with particularity, the complaint must allege 'facts as to time, place, and substance of the defendant's alleged fraud,' and 'the details of the defendants' allegedly fraudulent acts, when they

occurred, and who engaged in them." *Id.* at 1012 (*quoting U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc., supra*, 290 F.3d at 1310). It explained that "[l]iability under the False Claims Act arises from the submission of a fraudulent claim to the government, not the disregard of government regulations." 428 F.3d at 1012.

Clausen was again followed in *U.S. ex rel. Atkins v. McInteer, supra*. 470 F.3d 1350. There, the *qui tam* relator was a psychiatrist who alleged that two other psychiatrists and associated businesses had improperly sought reimbursement for services from Medicare and Medicaid. *Id.* at 1354. The court of appeals stated that, "[a]s the plaintiff did in *Clausen*, *Atkins* has described in detail what he believes is an elaborate scheme for defrauding the government by submitting false claims." *Id.* at 1359. "Just like the *Clausen* plaintiff, though, Atkins fails to provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes." *Id.* (emphasis in original). Accordingly, the court upheld the dismissal of the complaint because Rule 9(b)'s particularity requirement was not satisfied.

The Eleventh Circuit most recently reiterated its construction of Rule 9(b) in an FCA case

in *Mitchell v. Beverly Enterprises, Inc.*, *supra*, 248 Fed. Appx. 73, 2007 WL 2551404. In *Mitchell*, the Eleventh Circuit affirmed the dismissal of a *qui tam* complaint for failure to meet the particularity requirement because, although the relator included specific allegations of the defendant's illegal policies, he "fail[ed] to make specific allegations about [false] claims actually submitted to Medicare." 248 Fed. Appx. 73, *Id.* at *2. The short shrift given to the issue in Mitchell's unpublished decision demonstrates that the Eleventh Circuit views the law as well-settled.

In this case, the relators have provided detailed allegations of various schemes to promote Marinol's off-label use, but their allegations that the defendants' alleged illegal marketing campaign caused the submission of false claims for government reimbursement totaling millions of dollars are not supported by any facts concerning false claims actually submitted to the government for reimbursement. The relators concede that they cannot identify a specific false claim. Further, they have no information about the contents, or processing, of a false claim, such as who created a false claim or when false claims were created, the substance of the false representations, or alleged improper billing practices. In short, the relators lack knowledge of any false claim that was submitted to the government.

The relators speculate that a false claim must have been submitted to the government, arguing that "it is possible to draw a strong inference that false claims to Medicaid resulted from Solvay's off-label marketing campaign, because over the life of that illegal campaign, prescriptions for Marinol rose from 10,367 in 2000 to 124,208 in 2004, and Medicaid reimbursements for Marinol rose from $ 21.6 million in 2000 to $ 62 million in 2005" (Doc. 92, p. 9). However, the Eleventh Circuit will not infer that a false claim was submitted to the government, even when the relator provides detailed allegations of the fraudulent scheme that purportedly gave rise to the false claim. The court explained in *U.S. ex rel. Atkins v. McInteer*, *supra*, 470 F.3d at 1357(citation omitted):

> We cannot make assumptions about a False Claims Act defendant's submission of actual claims to the Government without stripping all meaning from Rule 9(b)'s requirement of specificity or ignoring that the "true essence of fraud" of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme.

See also U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc., *supra*, 290 F.3d at 1313, n.23 (the court

cannot presume billing policies or assume claims were actually billed to the government); *Corsello v. Lincare. Inc., supra*, 428 F.3d at 1013 ("Because it is the submission of a fraudulent claim that gives rise to liability under the False Claims Act, that submission must be pleaded with particularity and not inferred from the circumstances.").[8] Therefore, while the defendants' allegations may state a regulatory violation, they have not stated with particularity an FCA violation. Under *Clausen*, *Corsello*, and *Atkins*, the relators' second amended complaint is clearly insufficient and should be dismissed.

Notably, the relators in their memorandum make no meaningful attempt to distinguish these three decisions. At the outset of their argument, the relators point to proposed legislation that would eliminate a requirement that a person identify specific claims (Doc. 92, pp. 3-4). That unenacted proposal not only does not assist the relators, but it confirms the Eleventh Circuit's

[8] The defendants argue that an inference of wrongdoing under the FCA is further attenuated in this circumstance, as it requires the court to assume the existence of an off-label prescription which was written as a result of the defendants' illegal marketing campaign for a beneficiary of a government health care program, and that reimbursement for the cost of the drug was sought from the government on a claim form that falsified the fact that the prescription was for an off-label use (see Doc. 97. pp. 5-6).

requirement that specific claims must be identified.

Next, the relators urge a fresh reading of Judge Barkett's dissent in *Clausen*. *Id.*, p. 4. Obviously, a dissent does not reflect the law of the Eleventh Circuit.

The relators then seek support from *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S.Ct. 2499, (2007) (Doc. 92, pp. 4-10). That decision construed a scienter requirement under the Private Securities Litigation Reform Act. It did not address the FCA. Consequently, it provides no basis for this court to disregard the Eleventh Circuit's binding precedent in *Clausen*, *Corsello*, and *Atkins*.

At the hearing, relators' counsel emphasized the Eleventh Circuit's decisions in *Hill v. Morehouse Medical Associates, Inc.*, 2003 WL 22019936 (11th Cir. 2003)(unpub. dec.) and *U.S. ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349 (11th Cir. 2005). *cert. denied*, 549 U.S. 1027, (2006). Those decisions do not call *Clausen*, *Corsello*, and *Atkins* into question, and they certainly do not override them.

In *Hill*, the *qui tam* relator alleged that the defendant violated the FCA by routinely

submitting claims for payment to the government for tests that it did not perform. 2003 WL 22019936 at *1. The relator, who worked in the defendant's billing and coding department, supported her allegations with details of fraudulent billing, including, for example, her personal observations of employees changing diagnosis codes, after claims were rejected, to codes that would support Medicare reimbursement, and then resubmitting the claims for payment. *Id.* She also identified the employees who were responsible for the improprieties and how often they occurred. *Id.* at *1, *2. Despite the absence of an allegation of a specific false claim, the Eleventh Circuit found that the relator's complaint met the particularity requirement, as it included facts about the alleged fraudulent billing, the reliability of which were buttressed by the relator's firsthand observation of false claims in her role as a billing department employee. *Id.* at *5.

There is arguably some tension between *Hill* and *Clausen. Corsello* and *Atkins*.[9] In any event, *Hill* is clearly distinguishable from *Clausen*, *Corsello*, and *Atkins*, since *Hill's* allegations of false billing were

[9] The Eleventh Circuit noted in *Atkins* that *Hill*, as an unpublished opinion, is not binding precedent. 470 F.3d at 1358 n.15. Further, the court added that, even if *Hill* were a published opinion, the prior panel rule would dictate that *Clausen* supercedes *Hill* to the extent that *Hill* is inconsistent with *Clausen*. *Id.*

based upon personal knowledge and did not require any inference regarding the submission of false claims. There are no comparable allegations in this case and, thus, *Hill* provides the relators no support.

Similarly, *U.S. ex rel. Walker v. R&F Properties of Lake County, Inc., supra*, is inapposite. In *Walker*, the *qui tam* relator worked as a nurse practitioner for the defendant. She alleged that the defendant submitted false claims in violation of the FCA by improperly billing Medicare for nursing services as "incident to the service of a physician" even though no physician was present.[10] 433 F.3d at 1353-54. In her complaint, *Walker* alleged firsthand knowledge of actual false claims. Thus, she had no billing number and her nursing services were improperly billed at a higher rate through a physician's billing number even though she saw patients without physician supervision. *Id.* at 1360. Further, the complaint alleged that the office administrator confirmed to her that the defendant never billed nurse and nurse practitioner services in

[10] The *Walker* complaint alleged that, when a nurse works largely unsupervised. the treatment should be billed under the nurse's own identification number, for which the medical care provider would receive only eighty-five percent of the rate otherwise paid by the government. U.S. ex rel. *Walker v. R&F Properties of Lake County, Inc., supra,* 433 F.3d at 1352-53.

another manner. *Id.*

The relator's personal knowledge of the billing situation distinguishes *Walker* from *Clausen* and *Corsello*, as the Eleventh Circuit expressly pointed out. *Id.* As noted in *Atkins*, even if there were any inconsistency between *Walker*, on the one hand, and *Clausen* and *Corsello*, on the other -- and there does not appear to be any -- *Clausen* and *Corsello* would be the controlling decisions under the prior panel rule.

In all events, *Walker* does not support the relators' position in this case. There are no allegations in this case that are similar to the allegations in *Walker* based upon personal knowledge regarding the submission of false claims.

Consequently, *Clausen*, *Corsello*, and *Atkins* control the outcome in this case. Those cases require in an FCA case like this one allegations of the actual presentment of false claims. Because in this case the second amended complaint contains no such allegations, the complaint should be dismissed.

C. There are two ancillary matters that are appropriately addressed, even though the parties have not done so.

First, the relators have alleged claims on behalf of Illinois (Count II), California (Count III) and Massachusetts (Count IV) (Doc. 84, pp. 63-73). They have made no request that those counts remain pending if the FCA count is dismissed, and they certainly have not developed any argument supporting such a result. In particular, they have provided no basis for concluding that these state law claims could be considered on some type of supplemental jurisdiction after dismissal of the federal claim. In any event, in order to proceed in federal court, the state law claims would have to satisfy Rule 9(b)'s requirements, and, for the same reason that the federal claim is deficient under that rule, the state law claims are deficient as well.

Second, the relators have made no request to file another amended complaint. See *Wagner v. Daewoo Heavy Industries America Corp.*, 314 F.3d 541, 542 (11th Cir. 2002)(*en banc*). This is understandable since the relators acknowledge that they do not have the information necessary to cure the Rule 9(b) insufficiency. In other words, any attempt to remedy the deficiency would be futile.

IV.

For the foregoing reasons, I recommend

that the motion to dismiss (Doc. 88) be denied to the extent that it challenges subject matter jurisdiction. The motion should be granted, however, pursuant to Rule 12(b)(6), F.R.Civ.P., because the relators failed to state with particularity their FCA allegation that the defendants' illegal marketing scheme caused the submission of false or fraudulent claims to the government.

Respectfully submitted,

/s/ Thomas G. Wilson
THOMAS G. WILSON

UNITED STATES
MAGISTRATE JUDGE

DATED: AUGUST 1, 2008

NOTICE TO PARTIES

Failure to file written objections to the proposed findings and recommendations contained in this report within ten days from the date of its service shall bar an aggrieved party from attacking the factual findings on appeal. 28 U.S.C. 636(b)(1).

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JAMES HOPPER, et al.,

Plaintiffs,

v.

SOLVAY PHARMACEUTICALS, INC., et al.,

Defendants.

CASE NO: 8:04-cv-02356-T-23TGW

ORDER

Pursuant to 28 U.S.C. § 636 and Local Rule 6.01(b), the court referred (Doc. 98) the defendants' motion (Doc. 88) to dismiss to the United States Magistrate Judge for a report and recommendation. Magistrate Judge Thomas G. Wilson held a hearing on May 28, 2008, and subsequently issued a report and recommendation (Doc. 101). The

relators object (Doc. 104) to the Magistrate Judge's report and recommendation, and the defendants respond (Doc. 105).

A *de novo* determination of those portions of the report and recommendation to which the relators object reveals that the objections either are unfounded or otherwise require no different resolution of the motion. Accordingly, the relators' objections (Doc. 104) are **OVERRULED**. The Magistrate Judge's report and recommendation (Doc. 101) is **ADOPTED**. The defendants' motion to dismiss (Doc. 88) is **GRANTED IN PART** and **DENIED IN PART**.

To the extent the defendants' motion to dismiss challenges subject matter jurisdiction, the motion is **DENIED**. The defendants' motion to dismiss pursuant to Rule 12(b)(6), Federal Rules of Civil Procedure, is **GRANTED**. The relators' second amended complaint (Doc. 84) is **DISMISSED**. The Clerk is directed to (1) terminate any pending motion and (2) close the case.

ORDERED in Tampa, Florida, on September 8, 2008.

/s/ Steven D. Merryday
STEVEN D. MERRYDAY

UNITED STATES
DISTRICT JUDGE

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 08-15810

JAMES HOPPER and COLIN HUTTO

Plaintiffs-Appellants,

v.

SOLVAY PHARMACEUTICALS, INC., UNIMED PHARMACEUTICALS, INC., and the UNITED STATES OF AMERICA,

Defendants-Appellees.

Appeal from the United States District Court
for the Middles District of Florida

(December 4, 2009)

BEFORE: BLACK, WILSON and COX, Circuit Judges.

COX, Circuit Judge:

Solvay Pharmaceuticals, Inc. and its wholly owned subsidiary, Unimed Pharmaceuticals, Inc., manufacture and market Marinol, a synthetic form of THC, a hallucinogenic compound found naturally in marijuana. Qui tam relators James Hopper and Colin Hutto allege that Solvay engaged in an off-label marketing campaign to increase sales of Marinol for purposes not approved by the United States Food and Drug Administration. The relators sought recovery on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, for claims paid by government health programs as a result of the marketing campaign. The district court dismissed their action because the relators' Second Amended Complaint failed to plead the submission of specific false claims with particularity as required by Federal Rule of Civil Procedure 9(b). The relators appeal. We affirm.

I. BACKGROUND & PROCEDURAL HISTORY

Relevant sections of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, prohibit the presentment of false claims to the government and the use of false records or statements to get a false claim paid or approved. The Act may be enforced [*1322] through civil actions initiated by the government or suits by private individuals on behalf of the United States,

called qui tam actions. The private plaintiffs in qui tam actions are known as "relators," and the Act entitles them to a percentage of any recovery made on behalf of the government from a False Claims Act defendant.

We summarize the allegations of the relators in this case, Hopper and Hutto, from their Second Amended Complaint. Solvay employed the relators as sales representatives in its Mental Health Division. One of their duties was to implement what they allege to be an illegal marketing scheme for Marinol, a prescription drug manufactured and sold by Solvay.

In 1999, Solvay acquired Unimed, which owned the rights to manufacture and distribute Marinol, a synthetic form of THC, the active compound in marijuana.[1] Marinol is approved by the FDA for use as an appetite stimulant for AIDS patients and for the treatment of nausea and vomiting associated with cancer chemotherapy. According to the relators, Marinol is not particularly effective for these on-label

[1] Unimed, a wholly owned subsidiary of Solvay, is a named defendant in this case, but most of the allegations in the Second Amended Complaint refer to Solvay. It is unclear which of these allegations are alleged to be attributable to Unimed. References to Solvay hereafter include Unimed.

uses, so sales of the drug did not generate substantial profits for Solvay. To increase Marinol sales, the relators allege, Solvay implemented an off-label marketing campaign for the drug beginning in 2001. The relators assert that Solvay instructed its sales representatives to encourage physicians to prescribe Marinol for appetite loss in cancer patients and for treatment of nausea in HIV patients, purposes for which Marinol was not approved. Because the FDA prohibits the marketing of drugs for off-label uses, the relators allege that Solvay's marketing scheme was illegal.

The relators assert that sales generated from the marketing scheme caused the government to pay false claims through Medicaid and other programs that provide prescription drug benefits. The government does not knowingly pay for drugs through these programs if they are prescribed for off-label uses. The relators allege that the marketing campaign convinced doctors to prescribe Marinol for off-label uses, and claims were ultimately submitted by state health programs and other third parties to the federal government to pay for some of those prescriptions. The relators do not allege that Solvay itself submitted any false claims. Rather, they allege that every time federal funds were used to pay for an off-label prescription, the third party who requested payment

from the government made a false claim. (R.2-84 at 52-53.) Those false claims were attributable to Solvay, according to the relators, because the off-label marketing campaign caused the claims to be submitted against federal funds and because Solvay intended that its campaign cause the filing of false claims. (*Id.* at 60.) To support their allegations that the government paid false claims, the relators point to a marked increase in prescriptions for Marinol and an increase in Medicaid payments for Marinol between 2001 and 2005, years in which Solvay is alleged to have engaged in the marketing campaign.

In 2004, the relators filed a complaint based on these allegations, under seal, pursuant to the qui tam provisions of the False Claims Act. *See* 31 U.S.C. § 3730(b)(2) (requiring complaints be filed under seal and submitted to the government so it can conduct an investigation). They filed a First Amended Complaint in 2005. The Government was served with these complaints, investigated the allegations, and in 2006 ultimately chose not to intervene in the case. Shortly thereafter, the court ordered the lawsuit unsealed, and the relators sought leave to file a Second Amended Complaint ("Complaint"), which the court granted.

The Complaint alleges that Solvay

violated two subsections of the False Claims Act, 31 U.S.C. § 3729(a)(1) and (a)(2),[2] and parallel Illinois, California, and Massachusetts statutes. In a nutshell, it alleges that Solvay executed a sophisticated marketing plan for the purpose of inducing physicians to prescribe Marinol for uses not approved by the FDA, and this conduct "caused submission for reimbursement by Government Healthcare Programs of millions of dollars worth of prescriptions which were ineligible for such reimbursement." (R.2-84 at 2.) It also alleges that Solvay gave kickbacks to physicians and other healthcare providers to induce them to prescribe Marinol for off-label purposes. (*Id.* at 3.) The complaint does not identify any specific false claims presented to a government healthcare program or any person or entity who submitted a claim. Nor does it allege that Solvay intended that the government rely on the alleged false statements or records in deciding whether to pay claims. Instead, it alleges that Solvay's marketing campaign caused healthcare providers to

[2] The Fraud Enforcement and Recovery Act of 2009 amended and renumbered sections of the False Claims Act relevant to this appeal. Pub. L. No. 111-21, 123 Stat. 1617. These amendments, however, do not apply retroactively to this case. *See infra* note 3. Citations to the U.S. Code herein refer to the pre-amendment sections of the False Claims Act that apply to this case and do not reflect the 2009 amendments.

submit claims to state healthcare programs, and the state programs submitted false claims to the federal government. (*Id.* at 62.)

Solvay filed a motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1), and 12(b)(6). The Rule 12(b)(6) motion was grounded in an assertion that the relators failed to plead their allegations of fraud with particularity as required by Rule 9(b). Solvay also asserted that the court lacked subject matter jurisdiction over the case because some of the allegations were based on publicly disclosed information, and the relators were not the original source. *See* 31 U.S.C. § 3730(e)(4)(A) (creating jurisdictional bar to claims where plaintiffs are not the original source for information in the complaint). The district court referred the matter to a magistrate judge who recommended that the motion to dismiss be denied as to subject matter jurisdiction. He recommended, however, that the federal claims be dismissed for failing to satisfy Rule 9(b) because the relators failed to plead with particularity their allegations that Solvay's marketing scheme caused the submission of actual false or fraudulent claims to the government. (R.2-101 at 26-27.) The magistrate judge also recommended that the court decline to retain supplemental jurisdiction over the state law claims. The relators filed objections to the magistrate judge's

report, but the district court adopted it in full, dismissed the relators' federal claims with prejudice, and declined to exercise supplemental jurisdiction over the state law claims. The relators appeal.

II. ISSUE ON APPEAL & CONTENTIONS OF THE PARTIES

The sole issue on appeal is whether the Complaint, which does not include allegations of specific false claims or allege that Solvay intended for its statements to influence the government's decisions to pay any claims, satisfies the particularity requirements of Rule 9(b). The relators brought claims under 31 U.S.C. § 3729(a)(1) and (a)(2). Subsection (a)(1) makes liable any person who *presents, or causes to be presented*, a false or fraudulent claim. Subsection (a)(2) makes liable any person who knowingly makes, uses, or causes to be made or used, a false record or statement *to get a false claim paid or approved*. Solvay contends that to satisfy the particularity requirements under either 31 U.S.C. § 3729(a)(1) or (a)(2), a complaint must identify actual false claims. The relators counter that the requirements of Rule 9(b) may be satisfied as to subsection (a)(1) without identifying specific false claims as long as the complaint contains factual allegations which reliably indicate that false claims were submitted to the

government. As to subsection (a)(2), the relators argue that the presentment of a false claim to the government is not an element of the cause of action. So, they claim the particularity requirements of Rule 9(b) are satisfied by alleging that the defendants made false statements for the purpose of causing the payment of false claims. For claims under subsection (a)(2), the relators argue they need not allege that false or fraudulent claims were actually submitted to or paid by the government.

III. STANDARD OF REVIEW

We review de novo the grant of a motion to dismiss pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted. *Leib v. Hillsborough County Pub. Transp. Comm'n*, 558 F.3d 1301, 1305 (11th Cir. 2009).

IV. DISCUSSION

A complaint under the False Claims Act must meet the heightened pleading standard of Rule 9(b), which states "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." *See United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1309-10 (11th Cir. 2002) (noting "it was 'well settled'

and 'self-evident' that the False Claims Act is 'a fraud statute' for the purposes of Rule 9(b)") (citation omitted). A False Claims Act complaint satisfies Rule 9(b) if it sets forth "'facts as to time, place, and substance of the defendant's alleged fraud,' specifically 'the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them.'" *Id.* at 1310 (*quoting United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.*, 19 F.3d 562, 567-68 (11th Cir. 1994)).

The district court held that the relators' Complaint did not satisfy the particularity requirements of Rule 9(b) because it failed to include specific allegations of "the actual presentment of false claims." (R.2-101 at 25.) The court did not distinguish between the relators' allegations under 31 U.S.C. § 3729(a)(1) and their allegations under § 3729(a)(2). It reasoned that our precedents require all False Claims Act complaints to identify specific false claims, and the court appears to have concluded that these precedents apply equally to subsections (a)(1) and (a)(2) of the Act. Because the Complaint did not identify a specific false claim, the court found it did not satisfy Rule 9(b) and was subject to dismissal, pursuant to Rule 12(b)(6), for failing to state a claim upon which relief can be granted. (R.2-101 at 20.)

Indeed, in cases on which the district court relied, *Clausen; United States ex rel. Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005), *cert. denied*, 549 U.S. 810, 127 S. Ct. 42 (2006); and *United States ex. rel Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006), we did not differentiate between claims raised under subsection (a)(1) and subsection (a)(2) of the False Claims Act. The relators acknowledge that under subsection (a)(1), a plaintiff must prove that the defendant submitted or caused to be submitted a false claim to the government. But, they contend that submission of an actual false claim is not an element of a subsection (a)(2) claim. So, we will consider the claims separately.

A. 31 U.S.C. § 3729(a)(1)

31 U.S.C. § 3729(a)(1) contains a "presentment clause." It imposes liability on a person who "knowingly *presents, or causes to be presented*, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval." *Id.* (emphasis added). In *Clausen*, we explained that "[w]ithout the *presentment* of such a claim, while the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the

public fisc as required under the False Claims Act." 290 F.3d at 1311 (emphasis in original). We reasoned, "if Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government." *Id.* (emphasis in original).

In *Clausen*, the relator alleged that a medical testing corporation billed the government for unnecessary laboratory tests. *Id.* at 1303. The complaint included detailed allegations of a scheme to overcharge; it identified the patients who received tests, specified which tests were improper, and set forth the dates on which the procedures were performed. *Id.* at 1304-05. We upheld the dismissal of the complaint pursuant to Rule 9(b), however, because it failed to provide any information linking the testing schemes to the submission of actual false claims. *Id.* at 1313. The complaint included "the conclusory allegation that [the defendant] submitted bills to the Government 'on the date of service or within a few days thereafter.'" *Id.* We explained that if "Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion." *Id.*

We considered similar circumstances in

Corsello, in which a relator alleged that medical equipment companies engaged in kickback and referral schemes to falsify certificates of medical necessity to submit false claims for Medicare payments. 428 F.3d at 1011. Here, too, the relator failed to allege specific fraudulent submissions to the government. *Id.* at 1014. The relator argued "that a pattern of improper practices of the defendants leads to the inference that fraudulent claims were submitted to the government . . . ." *Id.* at 1013. Nevertheless, we upheld the dismissal of the complaint because it did not allege that "a specific fraudulent claim was in fact submitted to the government." *Id.* at 1014 (citing *Clausen*, 290 F.3d at 1311).

Similar issues were again presented in *Atkins*, where a relator alleged that psychiatrists improperly sought payments from Medicare and Medicaid for psychiatric services that were not actually rendered, were provided with substandard levels of care, and were medically unnecessary. 470 F.3d at 1354. The complaint in *Atkins* described "an elaborate scheme for defrauding the government by submitting false claims." *Id.* at 1359. It cited "particular patients, dates and corresponding medical records for services" that were not eligible for reimbursement. *Id.* We upheld the dismissal of the

complaint, however, because the relator failed "to provide the next link in the [False Claims Act] liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes." *Id.* (emphasis in original).

Like in *Clausen*, *Corsello*, and *Atkins*, the Complaint in this case offers detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe. The Complaint also includes what the relators describe as "a highly-compelling statistical analysis [that] renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of Marinol resulted from [Solvay's illegal marketing] campaign." (Appellants' Br. at 19.) But, the Complaint does not allege the existence of a single actual false claim. In fact, we are unable to discern from the complaint a specific person or entity that is alleged to have presented a claim of any kind, let alone a false or fraudulent claim.

The relators contend that the illegal marketing campaign first induced physicians to write off-label prescriptions for Marinol. Then, pharmacies and other healthcare providers submitted claims to various state healthcare programs for reimbursement. Finally, these state agencies submitted claims to the federal government for payment. (R.2-84 at 52-53.) The

Complaint does not identify specific persons or entities that participated in any step of this process. Nor does it allege dates, times, or amounts of individual false claims.

We will assume *arguendo* that when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription will be borne by the federal government, and when a claim is ultimately submitted to the federal government to pay for that prescription, 31 U.S.C. § 3729(a)(1) may have been violated. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732-33 (1st Cir. 2007) (suggesting that submitting off-label prescriptions for federal reimbursement could lead to the filing of false claims). Nonetheless, the relators' Complaint does not identify a single physician who wrote a prescription with such knowledge, does not identify a single pharmacist who filled such a prescription, and does not identify a single state healthcare program that submitted a claim for reimbursement to the federal government. The relators contend that their Complaint "contains factual allegations which reliably indicate that false claims were submitted to the Government." (Appellants' Br. at 16.) We disagree. The Complaint piles inference upon inference to suggest that Solvay's marketing campaign influenced some unknown third

parties to file false claims. We cannot conclude that the Complaint satisfies the particularity requirements of Rule 9(b) by offering "some indicia of reliability . . . of *an actual false claim* for payment being made to the Government." *Clausen*, 290 F.3d at 1311 (emphasis in original).

This is not a case like *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, in which a relator alleged personal knowledge of the defendants' billing practices that gave rise to a well-founded belief that the defendant submitted actual false or fraudulent claims. 433 F.3d 1349, 1360 (11th Cir. 2005). The relator in *Walker* pled a claim with particularity because the complaint included allegations grounded in first-hand knowledge that explained why she believed a specific defendant submitted false or fraudulent claims to the government. *Id.* Here, unlike in *Walker*, the relators do not allege personal knowledge of the billing practices of any person or entity. The complaint does little more than hazard a guess that unknown third parties submitted false claims for Medicaid reimbursement.

The relators' allegations pursuant to 31 U.S.C. § 3729(a)(1) are deficient under Rule 9(b). The "central question" in such a claim "is whether the

defendant ever presented [or caused to be presented] a 'false or fraudulent claim' to the government." *Clausen*, 290 F.3d at 1311 (quotation and citation omitted). Therefore, Rule 9(b) requires that actual presentment of a claim be pled with particularity. Because the relators' complaint fails to assert the "'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government," *Corsello*, 428 F.3d at 1014, the district court did not err by concluding the complaint failed to plead allegations of fraud with particularity.

B. 31 U.S.C. § 3729(a)(2)

In *Clausen*, we relied on the "presentment clause" of 31 U.S.C. § 3729(a)(1) to require that a complaint allege with particularity that the defendant submitted or caused to be submitted an actual false claim to the government. See *Clausen*, 290 F.3d at 1307 (quoting § 3729(a)(1)). In cases following *Clausen*, we have never explicitly considered whether the pleading requirements of § 3729(a)(1) apply with equal force to claims under § 3729(a)(2). *See, e.g.*, *Corsello*, 428 F.3d at 1012 (noting relator brought claims under both subsections (a)(1) and (a)(2), but not distinguishing between claims in analysis). Subsection (a)(2) does not contain a presentment clause. It imposes liability on any person who "knowingly

makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government."[3]

The relators contend that because subsection (a)(2) does not contain a presentment clause, proof that a false claim was submitted to the government is not an element of the cause of action. Plaintiffs are not required to allege what they are not required to prove. Therefore, the relators argue, their

[3] In May 2009, Congress enacted the Fraud Enforcement and Recovery Act, which amended 31 U.S.C. § 3729(a)(2) (2003), replacing the words "to get a false or fraudulent claim paid or approved by the government" with the words "material to a false or fraudulent claim." Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621. Section 4(f)(1) of the Act provides that this change "shall take effect as if enacted on June 7, 2008, and apply to all *claims* . . . that are pending on or after that date." *Id.* § 4(f)(1), 123 Stat. at 1625 (emphasis added). We interpret the word "claim" in section 4(f) to mean "any request or demand . . . for money or property," as defined by 31 U.S.C. § 3729(b)(2)(A) (as amended May 2009). While this *case* was pending on and after June 7, 2008, the relators do not allege that any *claims*, as defined by § 3729(b)(2)(A), were pending on or after June 7, 2008. Therefore, we conclude the Fraud Enforcement and Recovery Act does not apply retroactively to this case. *See United States v. Sci. Applications Int'l Corp.*, No. 04-1543, 2009 WL 2929250, at *13-14 (D.D.C. Sept. 14, 2009) (concluding Fraud Enforcement and Recovery Act not retroactive because no claims were pending on or after June 7, 2008).

Complaint need not allege that a false claim was submitted to the government. We agree that 31 U.S.C. § 3729(a)(2) does not demand proof that the defendant presented or caused to be presented a false claim to the government or that the defendant's false record or statement itself was ever submitted to the government. We conclude, however, that a plaintiff must show that (1) the defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government; and (2) the defendant's false record or statement caused the government to actually pay a false claim, either to the defendant itself, or to a third party. The Complaint fails to satisfy the first requirement; it does not allege that Solvay intended its false statements to influence the government's decision to pay a false claim. Therefore, even if we were to assume that it alleges with particularity that the government paid a false claim, the Complaint remains deficient.

In *Allison Engine Co. v. United States ex rel. Sanders*, ___ U.S. ___ , 128 S. Ct. 2123 (2008), the Supreme Court discussed the presentment requirement of § 3729(a)(2):

> [T]he concept of presentment is not mentioned in § 3729(a)(2). The inclusion of an express presentment requirement in

> subsection (a)(1), combined with the absence of anything similar in subsection (a)(2), suggests that Congress did not intend to include a presentment requirement in subsection (a)(2). . . . What § 3729(a)(2) demands is not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting "a false or fraudulent claim paid or approved by the Government."

__ U.S. at __ , 128 S. Ct. at 2129-30. The relators interpret this language to suggest that § 3729(a)(2) is violated as soon as a defendant makes a false or fraudulent statement for the purpose of causing the government to pay a false claim. In their view, § 3729(a)(2) may be violated even if a false claim is never submitted to or paid by the government. Essentially, the relators contend that *Allison Engine* teaches that subsection (a)(2) is an attempt provision, imposing liability for statements made with the intent to defraud the government, whether or not the government actually pays a false claim. We disagree; the language of § 3729(a)(2) suggests it demands proof that the government paid a false claim, and *Allison*

Engine does not cast doubt on this conclusion.

We have repeatedly held that the submission of a false claim is the "*sine qua non* of a False Claims Act violation." *Clausen*, 290 F.3d at 1311. Improper practices standing alone are insufficient to state a claim under either § 3729(a)(1) or (a)(2) absent allegations that a specific fraudulent claim was in fact submitted to the government. *Corsello*, 428 F.3d at 1014. Subsection (a)(2) relieves plaintiffs of the presentment requirement found in subsection (a)(1): the burden of proving that the defendant presented or caused to be presented a false claim to the government. But, the text of § 3729(a)(2)--proscribing false statements made "to get a false or fraudulent claim *paid or approved by the Government*"--suggests Congress intended this subsection to impose liability for false statements that actually cause the government to pay amounts it does not owe. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (citing 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.01[B], at 2-20 (2d ed. 2003) ("[A] plaintiff must also show that the defendant made or used . . . a false record in order to cause [a] false claim to be actually paid or approved.")). A defendant's false statements themselves need not be presented to the government, and the defendant need not personally submit a false

claim. Nevertheless, because the Act protects the government from loss due to fraud, and it is not "an all-purpose antifraud statute," *Allison Engine*, __ U.S. at __, 128 S. Ct. at 2130, the relators must show that the government paid a false claim to prove a violation of subsection § 3729(a)(2). Subsection (a)(2) is not, as the relators contend, a separate "attempt" provision of the False Claims Act. Nothing in *Allison Engine* conflicts with our conclusion. If *Allison* Engine speaks to this issue at all, it implies that under 31 U.S.C. § 3729(a)(2), a relator must prove that the government paid a false claim. The opinion states, "[o]ur reading of § 3729(a)(2) . . . gives effect to Congress' efforts to protect the Government from loss due to fraud but also ensures that 'a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct.'" *Id.* (citation omitted). If the government has not paid funds it does not owe, it has suffered no loss. To impose liability in such a case would do nothing to protect the government from loss due to fraud, and it would extend liability beyond the "natural, ordinary and reasonable consequences" of a defendant's conduct.

We hold that under § 3729(a)(2),[4] a

[4] Because the May 2009 amendments to 31 U.S.C. § 3729(a)(2) do not apply retroactively to this case, see *supra* note 3, we

plaintiff must prove that the government in fact paid a false claim.[5] Therefore, the relators' Complaint must allege with particularity, pursuant to Rule 9(b), that Solvay's false statements ultimately led the government to pay amounts it did not owe. The relators contend that they have done so. Their Complaint alleges that state health programs presented false claims of uncertain amounts on uncertain dates to the government, and this resulted in a marked increase in Medicaid payments. As discussed above, these allegations would be

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do not consider whether actual payment of a false claim is an element of this subsection as amended by the Fraud Enforcement Recovery Act of 2009.

[5] Our precedents interpreting 31 U.S.C. § 3729(a)(1) speak of the "submission" of false claims. *See, e.g., Clausen*, 290 F.3d at 1311 (discussing the submission and presentment of claims, not the payment of false claims). We have not explicitly considered whether a violation of § 3729(a)(1) occurs when a false claim is submitted, but the government does not pay the claim. The Third Circuit has held that payment of a false claim is not an element of a subsection (a)(1) claim, but actual payment is an element of a subsection (a)(2) claim. *Schmidt*, 386 F.3d at 242. Because the relators do not allege that Solvay submitted or caused to be submitted false claims that went unpaid, we do not address whether actual payment of a claim is an element of 31 U.S.C. § 3729(a)(1). We do consider whether actual payment of a claim is an element of 31 U.S.C. § 3729(a)(2), and we answer that it is an element.

insufficient to state a claim under subsection (a)(1) of the Act. Because liability under subsection (a)(1) is predicated upon the defendant itself submitting or directly causing the submission of a false claim, we require a plaintiff prove the "'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government." *Corsello*, 428 F.3d at 1014. But, under subsection (a)(2), a plaintiff must prove that the defendant made false statements to get a false claim paid or approved, not that the defendant caused the submission of the claim itself. So, our analyses in *Clausen*, *Corsello*, and *Atkins* do not necessarily foreclose the possibility that, for claims under subsection (a)(2), general allegations of improper government payments to third parties, supported by factual or statistical evidence to strengthen the inference of fraud, like those in the relators' Complaint, could satisfy the particularity requirements of Rule 9(b). The identity of the person or entity who submitted or caused to be submitted a claim for payment is not an element of a § 3729(a)(2) cause of action. So, in the appropriate case, we may consider whether the particularity requirements of Rule 9(b), as to the details of the alleged false claims at issue, are more relaxed for claims under 31 U.S.C. § 3729(a)(2) than for claims under § 3729(a)(1). *See United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 29 (1st Cir. 2009) (distinguishing between

qui tam actions alleging that the defendant made a false claim and actions in which the defendant induced third parties to file false claims; reasoning, "[i]n the latter context . . . a relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim") (quotation and citation omitted). Nevertheless, because we conclude the relators' Complaint in this case is deficient whether or not it alleges with particularity that a false claim was paid by the government, we do not reach this issue.

Whether the relators' Complaint alleges with particularity the payment of a false claim is a question we need not answer. Even if it did, the Complaint remains deficient because it fails to allege that the defendants intended for the government to rely on their false statements in deciding whether to pay a false claim.

To be liable under 31 U.S.C. § 3729(a)(2), a defendant must make a false record or statement "to get a false or fraudulent claim paid or approved by the Government." It is insufficient for a plaintiff to show merely that "a false statement *resulted in* the use of Government funds to pay a false or fraudulent claim." *Allison Engine*, ___U.S. at ___, 128 S. Ct. at 2128

(emphasis added). "Instead, a plaintiff asserting a § 3729(a)(2) claim must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." *Id.* at __, 128 S. Ct. at 2126.

The relators in this case claim that their Complaint "allege[s] copiously that [the] defendants intended their off-label campaign to cause the submission of false claims." (Appellants' Br. at 26.) But, their complaint does not link the alleged false statements to the government's decision to pay false claims. It fails to allege that the defendants intended for the government to rely on the substance of their off-label marketing campaign to decide to pay a claim. The Complaint alleges that Solvay intended for physicians to rely on their false statements to write off-label prescriptions. (R.2-84 at 2.) It does not allege that, aside from the unnamed physicians, any person or entity had knowledge of the off-label marketing campaign--not any pharmacists, state health programs, or significantly, the federal government. We cannot infer that because Solvay allegedly intended its marketing campaign to convince physicians to write off-label prescriptions, Solvay intended for that campaign to influence the government's decision to pay for those prescriptions.

> If a . . . defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim "by the Government." In such a situation, the direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability.

Allison Engine, __ U.S. at __, 128 S. Ct. at 2130.

To illustrate why the relators' Complaint is deficient, compare this case with *Duxbury*, a recent First Circuit case involving the off-label promotion of a prescription drug. In *Duxbury*, the relator "alleged facts . . . that support his claim that [the defendant] *intended* to cause the submission of false claims." 579 F.3d at 30 (emphasis in original). For example, the complaint in *Duxbury* alleged, in part, that the defendant pharmaceutical marketer gave a healthcare provider "more than $ 5,000 of [prescription drugs] *so that* [the provider] could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product and that [the provider] *was reimbursed* by

Medicare for the free [prescription drugs]." *Id.* at 31 (quotations omitted) (emphasis in original). The First Circuit found these and similar allegations supported the claim that the defendant intended its false statements to be material to the government's decision to pay a claim. *Id.* at 30 (citing *Allison Engine*, ___U.S. ___ at ___ , 128 S. Ct. at 2126). In contrast, the relators' Complaint in this case alleges that Solvay intended its statements to be material to physicians' decisions to write off-label prescriptions. It does not allege that Solvay intended its false statements to play any role in the government's decision to reimburse state health programs for the cost of those prescriptions. Because the relators failed to allege any connection between Solvay's alleged false statements and the government's decision to pay amounts it does not owe, the Complaint does not meet the particularity requirements of Rule 9(b).

V. CONCLUSION

Therefore, we affirm the district court's dismissal of the relators' federal claims for failure to comply with Federal Rule of Civil Procedure 9(b). And, we find no error in the court's declining to retain supplemental jurisdiction over the state law claims.

AFFIRMED.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA and the STATE OF CALIFORNIA, STATE OF MASSACHUSETTS, AND STATE OF ILLINOIS *ex rel.* JAMES HOPPER and COLIN HUTTO,

Plaintiffs and Relators,

v.

SOLVAY PHARMACEUTICALS, INC. and UNIMED PHARMACEUTICALS, INC.

Defendants.

Judge Steven D. Merryday
Magistrate Judge Thomas G. Wilson

Civil Action No. 8:04-cv-2356-T-23TGW

SECOND AMENDED COMPLAINT

I. INTRODUCTION

1. *Qui tam* Relators James Hopper and Colin Hutto bring this action on behalf of the United States against Solvay Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc. for treble damages and civil penalties arising from Defendants' conduct in violation of the Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA"). The violations arise out of requests for payment by Medicaid, Medicare, TRICARE, and other federally-funded government healthcare programs (hereinafter collectively referred to as "Government Healthcare Programs").

2. This action is also brought on behalf of the States of California (pursuant to the California False Claims Act, Cal. Gov. Code §§12650-12655), Illinois (pursuant to the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1-8); and Massachusetts (pursuant to the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A-O).

3. The gravamen of Relators' claims is that the Defendants developed and successfully executed a sophisticated marketing plan with the purpose of inducing physicians to prescribe the prescription drug Marinol®, which is synthetic marijuana, for uses which are neither FDA approved nor demonstrated to be

safe and effective. These uses are, principally, stimulation of appetite in cancer patients, and elderly and other persons in long-term care environments.

4. Defendants knew, when they initiated this illegal marketing program, that there was no credible scientific basis to justify their assertion that Marinol® is safe and effective for these off-label uses. Nonetheless, Defendants' conduct has caused submission for reimbursement by Government Healthcare Programs of millions of dollars worth of prescriptions which were ineligible for such reimbursement.

5. The off-label uses at issue were:

A. Not supported as medically acceptable by any major compendia such as those specified by 42 U.S.C. §1396r-8(g)(1)(B)(I) (describing federal Medicaid drug coverage);

B. Not capable of being medically accepted by any Medicare contractor based on supportive clinical evidence in certain peer-reviewed medical literature as set forth in 42 U.S.C. §1395(x)(1) and Medicare Carriers Manual §2049.4C

(describing Medicare anti-cancer drug coverage); and

C. Neither used in the treatment of a rare disease or condition for which it was FDA-approved or, alternatively, supported by reliable evidence as set forth in 32 C.F.R. §199.2 and TRICARE Policy Manual, Chapter 7, Section 2.1. (describing TRICARE drug coverage).

6. Moreover, the off-label uses marketed by Defendants are not supported by scientific studies, are contradicted by properly-conducted clinical trials, and were advocated by Defendants even though Defendants knew that other treatments worked better than Marinol®.

7. This Second Amended Complaint also describes unlawful remuneration, otherwise known as kickbacks, provided to physicians and other healthcare providers (hereinafter sometimes collectively referred to as "providers"), with a purpose of inducing them to prescribe Marinol® for off-label appetite stimulation in cancer and long-term care patients.

8. The kickbacks, which were an integral

part of a highly organized and orchestrated marketing campaign, included without limitation:

A. Providing physicians and other healthcare professionals with remuneration under the guises of "preceptorships," "honorariums," "speaker programs" and "travel summits."

B. Providing remuneration as inducements to physicians and other healthcare providers through organizations including but not limited to oncology nursing societies.

C. Providing lavish entertainment and other benefits including gifts to physicians and other healthcare providers.

D. Providing other benefits in the form of free breakfasts, lunches, and "ice cream days."

9. Relators have complied with all procedural requirements of the laws under which this case is brought.

II. JURISDICTION AND VENUE

10. Many of the acts proscribed by 31 U.S.C. §3729 *et seq.* and complained of herein occurred within the Middle District of Florida, and Defendants do business in the Middle District of Florida. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. 3732 (a), as well as under 28 U.S.C. § 1345. This Court has supplemental jurisdiction over the state law pursuant to 31 U.S.C. §3732(b).

11. Venue lies under 31 U.S.C. § 3732(a).

12. The facts and circumstances which give rise to Unimed and Solvay's violations of the False Claims Act have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

13. Relators are the original source of the information upon which this complaint is based, as that phrase in used in the False Claims Act and other laws at issue herein, and made pre-filing disclosures to the extent required by law.

III. PARTIES

14. Relator James Hopper, an Alabama resident, was a Sales Representative in Solvay's Mental Health Division from October 1999 until he resigned in December 2005. The entire mental health sales force was assigned to the hematology/oncology division from February 2002 until May 2003. Mr. Hopper was District Sales Trainer from January 2002 until December 2002. In his positions as sales representative and sales trainer, he was fully trained in and required to implement and report regarding the success of the unlawful off-label marketing plan described in this Complaint.

15. Relator Colin Hutto, an Alabama resident, was a Sales Representative in Solvay's Mental Health Division from early 1999 until late 2003. In that position, he was fully trained in and required to implement and report regarding the success of the unlawful off-label marketing plan described in this Complaint.

16. Relators bring this action based on their direct knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4),

and Relators are an original source of the facts alleged in this Complaint.

17. Defendant Solvay Pharmaceuticals, Inc. is the U.S subsidiary of Solvay Pharmaceuticals. Its headquarters are located at 901 Sawyer Rd., Marietta, GA 30062, and it is organized under the laws of the State of Delaware.

18. Defendant Unimed Pharmaceuticals, Inc. is an Illinois Corporation with its corporate headquarters located at 901 Sawyer Rd., Marietta, GA 30062. Unimed was acquired by Solvay in July 1999, and remains its wholly-owned subsidiary.

19. Non-party Roxane Laboratories, Inc. (hereinafter "Roxane") is a prescription specialty and generic pharmaceutical manufacturer based in Columbus, Ohio. Roxane is a subsidiary of Boehringer Ingelheim Corporation of Ridgefield, Connecticut. Roxane served as Unimed's co-promoter for Marinol® until 2001.

20. At all times relevant hereto, Defendants acted through their agents and employees, and the acts of Defendants' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were,

on information and belief, established and/or ratified at the highest corporate levels of Defendants.

IV. THE REGULATORY ENVIRONMENT

A. Regulation of Prescription Drug Sales and Marketing

21. The United States Food, Drug and Cosmetic Act (FDCA) establishes the framework for regulation of, *inter alia*, the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce. When the United States Food and Drug Administration ("FDA") approves a drug, it approves the drug only for the particular use for which it was tested, but after the drug is approved for a particular use, the FDCA does not regulate how the drug is prescribed. Thus, a drug that has been tested and approved for one use only can also be prescribed by a physician for another use, known as an "off-label" use.

22. Under the FDCA, new drugs cannot be distributed into interstate commerce unless and until the manufacturer has demonstrated to the Food and Drug Administration (FDA) that the drug is safe and effective.

23. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It therefore is illegal for a drug manufacturer and its sales representatives to initiate discussions with medical professionals regarding any off-label use of the drug.

24. The dissemination of information or materials by a pharmaceutical manufacturer of any unapproved or off-label use, also known as "misbranding," constitutes unlawful promotional advertising of the drug and violates the FDCA.

25. Reasons why Congress made off-label marketing and promotion by drug manufacturers illegal include, without limitation, the following:

(A) Off-label promotion diminishes or eliminates the drug manufacturer's incentive to study the use of its drug and obtain definitive safety and efficacy data;

(B) Off-label promotion harms patients as the result of unstudied uses that lead to adverse results, or are ineffective;

(C) Off-label promotion diminishes the use of evidence-based medicine; and

(D) Off-label promotion erodes the efficacy standard in medicine.

B. The Anti-kickback Act

26. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and Tricare.

27. The Anti-Kickback Act is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

28. Every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

29. The Anti-Kickback Act prohibits

suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a purpose of the payment is to influence the provider's prescribing habits or to gain favor for its product over the product of any competitor.

30. Examples of activities prohibited by the Anti-Kickback Act include, without limitation, payments for sham consulting services, illusory training sessions, bogus research and educational grants, bogus speaking fees, entertainment, travel and lodging expenses, expensive meals and wine, and other gifts and discounts. These activities are particularly suspect if the drug manufacturer selects the physician based upon perceived ability or potential to prescribe the company's products rather than professional qualifications or services actually rendered to the company.

31. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have acted to prevent manufacturers from employing indirect methods to accomplish the same end. For example, FDA regulates two of the most prevalent indirect promotional strategies: (A) manufacturer dissemination of medical and scientific publications

concerning the off-label uses of their products; and (B) manufacturer support for Continuing Medical Education ("CME") programs that focus on off-label uses.

32. With regard to the first practice—disseminating written information—the FDCA allows a manufacturer to disseminate information regarding off-label usage only in response to an "**unsolicited request** from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; and has provided the materials to the FDA prior to dissemination. The materials must be submitted in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c);360aaa-1.

33. In sum, the off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body—the FDA.

C. Reimbursement Criteria Used by Government-funded Health Care Programs

34. The federal government pays for prescription drug benefits under a variety of health care programs. One of these programs is Medicaid, which provides health care coverage, including prescription drug benefits, for the poor and disabled. The Medicaid program, which is administered by the Centers for Medicare and Medicaid Services (CMS), is funded in part by the federal government. Other government-funded health care programs that pay for prescription drugs include Medicare, CHAMPUS/Tricare, the Veteran's Health Administration, Federal Employees' Health Benefits Program, and the Indian Health Bureau.

35. While each government-funded health program establishes its own reimbursement criteria, none knowingly pay for medications that are not prescribed for a medically accepted indication, or that are prescribed as a result of false or misleading information disseminated by the pharmaceutical manufacturer. In addition, none of the government-funded health care programs willingly pay for prescription drugs the prescribing of which was the result of, or was influenced by, unlawful inducements

from or unlawful marketing activities by the pharmaceutical manufacturer.

V. FACTS

A. Marinol®

36. Marinol® (dronabinol) is a synthetic form of delta-9-tetrahydrocannabinol (THC), the major active component of marijuana. It is an abusable hallucinogenic drug regulated under Schedule III of the Controlled Substances Act. The terms "Marinol®," "dronabinol," and "delta-9-tetrahydrocannibinol" refer to the same thing.

37. Identified side effects of Marinol® usage include anxiety, confusion, emotional lability, hallucinations, cardiac events, and seizures, among others. Those prescribed Marinol® are warned not to drive or operate equipment "until it is established they are able to tolerate the drug and to perform such tasks safely," and Marinol® is to be prescribed with caution for patients with psychiatric issues or a history of substance abuse.

38. Marinol® was first approved in 1985 for the treatment of "nausea and vomiting associated with cancer chemotherapy in patients who have failed to

respond adequately to conventional antiemetic treatments."

39. In January, 1991, Marinol® received FDA approval and Orphan Drug designation for "anorexia associated with weight loss in patients with a confirmed diagnosis of AIDS." In 1992, FDA approved a supplemental new drug application for Marinol® for treatment of "anorexia associated with weight loss in patients with AIDS." This condition is sometimes called "AIDS wasting syndrome."

40. The various available strengths of Marinol® and exemplar costs as of March 2007 are:

Capsule strength	30 Capsules
2.5 mg white capsules 0051-0021-21	$183.50
5 mg dark brown capsules 0051-0022-11	$353.64
10 mg orange capsules 0051-0023-21	$663.45

41. Defendant Unimed has held the New Drug Application ("NDA") for Marinol® since it

received FDA approval for one limited use in 1985. That 1985 approval was for a very narrow indication: Treatment of refractory nausea and vomiting secondary to cancer chemotherapy. This condition is sometimes called Chemotherapy Induced Nausea and Vomiting, or "CINV." "Refractory" means that Marinol® is not to be prescribed unless and until the patient has not responded to treatments which are approved for "first line" usage. Because there are many safe and effective first-line treatments for CINV, the market for Marinol® in the treatment of CINV always has been small.

42. In a May 1985 letter to Unimed discussing its decision on the NDA, the FDA explained the strict limitation on the indication this way: "This restriction is required because a substantial proportion of patients treated with Marinol® can be expected to experience disturbing psychotomimetic reactions not observed with other antiemetic agents." "Psychomimetic" means "producing effects (as hallucinations or paranoid delusions) that resemble or are identical with psychotic symptoms."

43. The FDA continued: "Because of its potential to alter the mental state, Marinol® is intended for use under circumstances that permit close supervision of the patient by a responsible

individual."

44. The FDA advised Unimed that Marinol® "is contraindicated in patients whose nausea and vomiting arises from any cause other than cancer chemotherapy."

45. Roxane co-promoted Marinol® under license from Unimed from about July 1986 until on or about December 31, 2000.

46. Marinol® was never widely used for its indicated conditions.

47. A 1999 report by the U.S. Department of Health and Human Services stated:

> According to the National Cancer Institute, other [than Marinol®] anti-emetic drugs or combinations of antiemetic drugs have been shown to be more useful than smoked marijuana or synthetic THC as "first-line therapy" for nausea and vomiting caused by anticancer drugs. Examples include drugs called serotonin antagonists, including ondansetron (Zofran) and granisetron (Kytril), used alone or

> combined with dexamethasone (a steroid hormone); metoclopramide (Reglan) with diphenhydramine and dexamethasone; high doses of methylprednisolone (a steroid hormone) combined with droperidol (Inapsine); and prochlorperazine (Compazine). Research with other agents and combinations is under way to determine their usefulness in controlling chemotherapy-induced nausea and vomiting.

"HHS Fact Sheet," U.S. Department of Health and Human Services July 13, 1999.

48. At least the following prescription drugs are FDA-approved as first-line antiemetics for CINV patients:[6]

Reglan® (metoclopramide Hcl), approved in

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[6] These drugs are also commonly used as antiemetics to treat nausea and vomiting secondary to chemotherapy:

Compazine (prochlorperazine), approved in 1956

Dexamethasone (generic), approved in 1962

Ativan (lorazepam), approved in 1977

1979

Zofran® (ondansetron Hcl), approved in1992
Kytril® (granisetron Hcl), approved in1993
Anzemet® (dolasetron mesylate), approved in 1997

Emend® (aprepitant), approved in 2003
Aloxi® (palonosetron HCl), approved in 2003

49. From the earliest days of the marketing of Marinol®, Unimed and its agents attempted to induce physicians to prescribe it for off-label uses beyond its FDA-approved uses. For example, in February 1993, as part of a review of proposed marketing materials, FDA advised defendant Unimed that it could not market Marinol® as "the first product in a new therapeutic class of appetite stimulants" because "[t]his implies a broader indication than the one received by Marinol®" which was for "a very specific patient population[,] and all promotion should be restricted to that population."

50. In April 1993, FDA advised Roxane, defendant Unimed's marketing agent, that it was "unacceptable to make claims such as: ' . . . for the treatment of anorexia in patients with AIDS'" and advised that the claim that Marinol® "Restores the Appetite" was "false and misleading."

51. FDA further advised that Roxane, as Unimed's marketing agent, could not assert that "appetite improvement was sustained over time" in the AIDS-anorexia-with-weight-loss population, because the appetite improvement "was not statistically significant compared to placebo."

52. Notwithstanding FDA's firm directives regarding acceptable marketing claims, Roxane's and Unimed's initial marketing materials were determined by the FDA to be "false and/or misleading."

53. In a June 22, 1993 letter to the President of Roxane, FDA advised that Roxane's advertisement for Marinol® in the March 1993 Journal of Clinical Oncology was promoting unapproved uses of Marinol® by failing to advertise that the product was approved only for *refractory* nausea and vomiting in chemotherapy patients. FDA asserted that the "failure to disclose this limitation in regard to the appropriate patient population strongly implies or suggests Marinol® use in a broader population than is indicated in the approved labeling."

54. FDA also found that Roxane made inaccurate and false "comparative claims to conventional antiemetic therapies" and failed to

disclose the risks associated with Marinol® use.

55. Roxane was ordered by FDA to provide written notice to all persons to whom it had promoted Marinol®, and to place paid advertisements in all journals in which the false and misleading advertisements had appeared.

56. As a result of FDA's action, Roxane had to send "Dear Physician" letters to more than 33,000 practitioners and place corrective ads in several medical journals.

57. Even with its illegal promotions, Roxane's sales of Marinol® were moribund through the 1990s. Medicaid reimbursements for Marinol® for the period 1991-99 were:

1991	$639,163.95
1992	$1,547,723.66
1993	$4,258,736.51
1994	$5,822,209.99
1995	$6,315,966.15
1996	$8,405,099.61
1997	$9,701,667.41
1998	$11,968,264.14
1999	$15,716,311.24

58. When Solvay acquired Unimed in or about July 1999, it knew that the market for Marinol's® oncology indication was modest at best, because Marinol® is only indicated in "refractory" patients--that is, cancer patients who have nausea and vomiting secondary to chemotherapy *and* have failed to respond adequately to "first-line" antiemetic treatments. Since on or about January 1, 2001, Marinol® has been marketed, promoted and distributed exclusively by Solvay.

59. Also in 1999, the Drug Enforcement Agency reclassified Marinol® from a Schedule II controlled substance to a Schedule III controlled substance. The effect was to make it easier for doctors to prescribe Marinol®.

60. Nonetheless, the market for Marinol® remained small, primarily because Marinol® was not generally viewed by oncologists as a useful product for its on-label use. Defendant was aware that Marinol® was held in such low disregard for treatment of nausea that it should be considered a new drug.

61. Among the 120 physicians who wrote the most prescriptions for Marinol® during the period 2000-2004, 58 (49%) were oncologists. Only 14 (24%) of these 58 oncologists wrote any prescriptions for

Marinol® in 2000, and of those 14, six wrote three or fewer prescriptions. The total number of Marinol® prescriptions written by the 58 oncologists in 2000 was 88.

62. In 2001, Solvay began to develop a vigorous off-label marketing campaign for Marinol®. In that year, the same 58 oncologists wrote 765 prescriptions—an 869% increase from 2000.

63. Solvay knew that a principal weakness of Marinol® from a marketing perspective was the fact that it was FDA-approved only for refractory CINV and AIDS wasting with appetite loss.

64. Despite FDA's mandated limitations, Solvay promoted Marinol® to fill what it decided were "unmet patient needs" in connection with appetite stimulation in cancer patients; in the long-term care market; and for HAART-induced nausea in patients with HIV/AIDS.

B. Defendants' Illegal "Dual Indication" Off-Label Marketing Program

65. Despite the FDA's repeated admonitions to Unimed and its sales agent that it was illegal to market Marinol® as an "appetite stimulant" outside

the "very specific patient population" for which it was approved—*i.e.*, for AIDS patients with anorexia and associated weight loss—Solvay launched an aggressive marketing campaign with the purpose and effect of causing physicians to prescribe Marinol® for use as an appetite stimulant in patients with appetite loss due to cancer, aging, and other conditions.

66. Megace® oral suspension (megestrol acetate), manufactured by Bristol-Myers Squibb Company, "is indicated for the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of acquired immune deficiency syndrome (AIDS)." All three of the Drug Compendia specified by Congress as authoritative in both Medicaid and Medicare (Part D) programs, list Megace® as effective in the treatment of anorexia/cachexia in cancer patients. Clinical research appearing in peer-reviewed medical literature also concludes that there is substantial evidence of effectiveness. Even so, Megace® is not actively marketed as an appetite stimulant in off-label markets such as cancer patients for, unlike Marinol®, there are generics available and its market-leading sales are driven by the product itself, as opposed to illegal marketing by a huge sales force.

67. Oncologists were the most consistent

prescribers of Megace® and defendants focused their Marinol® marketing efforts into the oncology community with special focus on physicians who were high prescribers of Megace®. Defendants identified these physicians by purchasing data which identified by name each physician who prescribed Megace®. Because Solvay essentially abandoned the marketing of Marinol® for the approved indication of refractory CINV, it made no sense for its sales representatives to call on oncologists. The number of Marinol® prescriptions written for use as an antiemetic in refractory CINV was minuscule, because it was not approved for first-line use and there were first-line antiemetics which were safer and more efficacious than Marinol® for refractory CINV.

68. In fact, Solvay devoted almost no time in sales training or marketing on this indication: The only reason Defendants targeted oncologists was for the off-label appetite stimulation use.

69. To express or imply that Marinol® worked well as an appetite stimulant in the cancer patient population, or was as good as Megace®, without any legitimate clinical-trial evidence, was false and misleading and constituted illegal misbranding under the FDCA. Moreover, Defendants lacked substantial clinical evidence of effectiveness to

support the statements and implications that Marinol® was effective as an appetite stimulant in any patient population other than those patients with HIV/AIDS.

70. In June 2001, Defendants decided to target oncologists and cancer hematologists in order to "educate" them about the role of cannabinoids as standard therapy for appetite stimulation despite knowing that Marinol® had no indication for and was not safe and effective as standard therapy for appetite stimulation.

71. The sole FDA-approved indication for Marinol® in the world of oncology is as second-line treatment for refractory nausea and vomiting in chemotherapy patients.

72. Defendants viewed the appetite-stimulation market as being worth over $100 million per year and growing.

73. Defendants viewed their oncology market as including the 80% of cancer patients who suffer from nausea and vomiting, regardless whether they were undergoing chemotherapy. This is patently off-label, given the indication for only refractory CINV.

74. Defendants were aware that Marinol® was not approved for treatment of cancer-related cachexia or anorexia.

75. Defendants were aware that Marinol® was not especially effective even for the refractory treatment of CINV, for which it was approved.

76. Defendants were and are fully aware that it has not been scientifically established that Marinol® is safe and effective treatment for appetite loss in cancer patients.

77. By no later than mid-2001, Defendants all but abandoned the marketing of Marinol® for its FDA-approved, second-line CINV indication, switching its marketing focus entirely to the unapproved and ineffective uses of Marinol® described in this Complaint.

78. Beginning in or about July 2001, Defendants increased the Marinol® sales force from 75 to 120, with the primary focus being detail efforts focused on Oncologists, Hematologists, and Oncology Nurses.

79. Solvay's marketing program was structured in part around the fact that Marinol® has

nearly universal reimbursement/coverage from 3rd party payors, so that off-label prescriptions could be paid for by, *inter alia*, Medicaid, Medicare, and other publicly-funded health care programs.

80. Defendants hoped that their off-label marketing campaign would result in a substantial increase in Marinol® sales from 2001 to 2002.

81. Defendants' objective for Marinol® in 2002 was expansion of the appetite stimulation market and establishment of Marinol® as a first-line therapy for appetite stimulation.

82. Neither Unimed nor Solvay has ever requested that the FDA approve Marinol® as an appetite stimulant in cancer patients.

83. Neither Unimed nor Solvay has ever conducted, sponsored, or funded proper clinical studies to determine whether Marinol® is a safe and effective appetite stimulant in cancer patients—first-line or otherwise.

84. Defendants marketed Marinol® as being the "agent of choice for improving quality of life in Cancer and HIV/AIDS patients because it is the only medication that collectively treats appetite loss,

nausea and mood."

85. Marinol® is not safe and/or effective as an appetite stimulant in cancer patients, nor does it treat appetite loss in cancer patients.

86. Marinol® does not improve the quality of life in cancer patients.

87. Marinol® does not improve mood in cancer patients and has not been FDA approved to treat mood or "quality of life" deficits in such patients.

88. Marinol® has never been approved by the FDA as an appetite stimulant in cancer patients.

89. Notwithstanding the fact that the new marketing campaign for Marinol® was constructed of lies and illegal marketing statements, Defendants implemented it with vigor.

90. Defendants focused on blending the two Marinol® indications because it concluded that doctors did not distinguish between the two approved uses of the drug.

91. Defendant Solvay knew that physicians considering the use of Marinol® believed that there

was insufficient clinical data to support the use of the drug in off-label circumstances, and constructed its marketing plans with the purpose and intent of undermining that objection, while never developing any new clinical data.

92. In late 2001, Relators were provided a document captioned "Medical Liaison—Marketing Teleconference." The document identifies the "appetite stimulation market" as $226,000,000 per year, admits that there is "no new clinical data or indications," asserts that "Mood Elevation" is an "Opportunit[y]" for Marinol®," identifies "[l]abeling limitations" and "thin, dated" clinical data as "Weaknesses," and directs sales representatives to "[p]ress interest in cannabinoids, chronic disease, QOL ("quality of life")."

93. The document reiterates the false and misleading claim that "Marinol® is the drug of choice for improving quality of life in Cancer and HIV/AIDS patients because it is the only medication that treats appetite loss, nausea and mood."

94. The document notes that there is widespread approval of Marinol® for third-party reimbursement, and states that one-third of Marinol® sales in the Appetite Stimulant market for the period

January to June 2001 was reimbursed by Medicaid—and that Marinol® had a 21.4% share of the Medicaid Appetite Stimulant market.

95. Payment for Marinol® by public funding sources, including Medicaid, increased dramatically once the new marketing campaign was introduced. Medicaid alone reimbursed pharmacies for $36,197,809 in Marinol® sales in 2002, compared with $17,309,950 in Marinol® sales in 2001—a 109% increase. Defendants in 2002 estimated the daily cost of Marinol® treatment for appetite stimulation at $8.33.

96. In January 2002, results of a multi-institutional double-blind randomized clinical trial were published by Dr. Aminah Jatoi and others. Jatoi, *et al.*, "Dronabinol Versus Megestrol Acetate Versus Combination Therapy for Cancer-Associated Anorexia: A North Central Cancer Treatment Group Study," 20 J. Clin. Oncology 567 (2002). Dr. Jatoi is Professor of Oncology at the Mayo Clinic College of Medicine in Rochester, Minnesota.

97. Dr. Jatoi asserts, and it appears to be undisputed, that his was the first clinical study to compare Marinol® with Megace®. On information and belief, it is also the only such study.

98. Dr. Jatoi's research demonstrated that megestrol acetate (Megace®) was substantially more effective than Marinol® in treatment of cancer-associated anorexia, and that adding Marinol® to treatment with Megace® did not improve outcomes.

99. Administering Marinol® instead of Megace® to patients suffering from cancer-associated anorexia jeopardizes the health of those patients.

100. Defendants' sales representatives, including Relators, were instructed in an electronic mail message "NOT to initiate conversation" [regarding the Jatoi study] with your physicians under any circumstances."

101. Defendants were aware that the clincial data supporting the use of Marinol® was thin and dated, and that the Jatoi study showed that Megace® was superior. However, Defendants have never conducted or sponsored any study to demonstrate that Dr. Jatoi's results were incorrect, and no such study, from any source, exists.

102. Solvay considered the appetite stimulation market in oncology and long-term care to be the primary opportunities for Marinol®, and knew that obstacles to success included limited clinical data,

perceived low efficacy, and limitations imposed by the drug's FDA-approved label.

103. Solvay Management knew that there were problems in marketing Marinol® which included limited clinical data, perceived low efficacy, and identified labeling and indication limitations as the leading weaknesses of Marinol®.

104. In or about July 2002, a Solvay sales representative presented a Business Update using slides which were distributed to Relators.

105. The sales representative's presentation included descriptions of his sales contacts with physicians, who he called "Kahunas." One "Kahuna" was Dr. [117-01], an oncologist/hematologist in Orange County, California. Dr. [117-01] was reported to be "very open to using Marinol®. His biggest hurtle (*sic.*) has been selling the product to his patients." (The names of physicians in this Second Amended Complaint have been kept confidential at the request of Solvay.)

106. Dr. [117-01] qualified as a "Kahuna" by, according to defendants' records, prescribing Marinol® a total of 21 times from 2002 to 2004.

107. Another "Kahuna" discussed by the sales representative was an Oncologist, Dr. [119-01]. The sales representative described his sales tactics thusly:

> I have completed a preceptorship with Dr. [119-01] and his nurse. I have spent time helping Dr. [119-01]'s front office staff (answering phone and filing) while waiting to talk to him. I have spent a lot of time developing strong relationships with this office and the treatment oncology nurses. I have done two lunches in the office. I bring Starbucks coffee to the treatment room, and have had 'ice cream' days in their office. Dr. [119-01] is a strong supporter of Marinol® and his nurse is suggesting more patients be put on it.

108. With respect to "Kahuna" Dr. [120-01], the sales representative wrote:

> I have completed a preceptorship with Dr. [120-01]. I have spent a lot of time developing strong relationships with this office and the treatment oncology nurses. I have done two lunches in the office. I bring Starbucks coffee to the treatment

> room, and have had 'ice cream' days in their office . . . I have made progress with the nurses in the treatment room who are supporters of Marinol®. I am hoping that they will help influence Dr. [120-01] to use more of the product. My goal is to get Dr. [120-01] to write at least two scripts of Marinol® a month. He wrote 0 in Jan-Feb. I got him to write one in March.

109. Dr. [120-01] prescribed Marinol®, according to defendants' data, 12 times in 2002, 11 times in 2003, and 14 times in 2004.

110. Defendant viewed sales representatives, such as Relators, also called "Detailers," as critical to market expansion, concluding that there was a direct relationship between the number of times sales representatives visited a physician and her prescribing habits.

111. Defendant knew that Marinol® had limited market potential for treatment of nausea and vomiting, and exhorted its marketing representatives that the market potential for Marinol® in treating anorexia was much larger than nausea and vomiting.

112. Detailers understood that Solvay's Marinol® marketing materials were most effective among physicians who had limited familiarity with Marinol®.

113. Solvay spent millions of dollars in 2002 to "educate" heath care providers about the use of Marinol as first-line appetite-stimulation therapy in cancer, HIV/AIDS, and long-term care markets—all of which were off-label uses.

114. In 2002 Solvay arranged and paid for medical education programs as another means of promoting Marinol as an appetite stimulant for all patient populations, for developing opinion thought leaders in the physician community and for continuing to provide focus on off-label uses. These programs were seen as a way to overcome the lack of clinical data supporting the efficacy of Marinol.

115. The 58 oncologists among the 120 top writers of Marinol® prescriptions for 2000-2004 wrote 1,278 Marinol® prescriptions in 2002, 167% of the 2001 figure and a 1,452% increase compared to 2000.

116. Oncologists and hematologists wrote about 13% of Marinol® prescriptions in 2000, more than 56% in 2001, and almost 49% in 2002.

117. Solvay misrepresented the results of various clinical trials which had been conducted specific to patient populations as applying to all patient populations and thus promoted Marinol's "unique multiple benefits" of increasing appetite, reducing nausea and vomiting, and improving weight and mood to cancer patients, AIDS patients and long-term-care patients.

118. Sales representatives, including Relators, were routinely exhorted to push Marinol® as an appetite stimulant.

119. Sales representatives were regularly provided with data identifying the physicians on whom they were to call. These data included the physicians' actual prescribing practices with respect to Marinol® and Megace®, which Defendants purchased in order to target physicians in order to convince them to abandon Megace® in favor of Marinol®.

120. Relators' Regional Business Director used a voice message distributed to all or many sales representatives, including Relators, to congratulate a sales representative from Kansas City for successfully promoting Marinol® to a local oncologist as an appetite stimulant. The message, which was left in early 2003,

stated:

> Good afternoon, this message going to the entire Southwest Region. How's everyone doing out there? Hey, I am here to give you an excel success story today. And today's story focuses on [a sales representative] from Kansas City, Missouri. [The sales representative] called on a doctor [133-01], who is a gynecologist. Gee, you'd think he'd be an orthopedic surgeon with a name like that! Anyway, he called on Dr. [133-01] after our POA meeting in January. He positioned Marinol as an alternative to Megace for appetite stimulation in his female patients that presented with an estrogen receptive positive cancer. Well, [the sales representative] differentiated Marinol from Megace concerning our non-hormonal message, and then went on to explain our efficacy using the core detail pieces and followed up by covering both the Lane and Beal 95 studies. Hey great job [sales representative]—way to go! You've got what it takes to excel, and you're definitely in the game. Thank you.

121. Solvay specifically identified increasing off-label use of Marinol® as a primary goal.

122. Solvay specifically identified the narrow label indications approved by the FDA as a weakness of Marinol®.

123. Other weaknesses Solvay identified included the superiority of Megace® and the Jatoi study.

124. By late 2003, Defendants' Marinol® marketing force had grown to 150, double the size of the number of sales representatives at the beginning of 2001.

125. Solvay continued in 2003 to support medical education programs which focused onoff-label marketing for Marinol®.

126. Solvay began to market Marinol® to AIDS practitioners based on the claim that it effectively increased appetite, provided a reduction in nausea and produced trends toward improved weight and mood.

127. These are the same marketing messages which the FDA found to be false and misleading in

1993, and which Unimed agreed not to pursue.

128. Additionally, the FDA approved Marinol® exclusively for AIDS patients with AIDS-induced anorexia and weight loss.

129. The FDCA does not permit pharmaceutical companies to reposition drugs for different indications in different phases of disease management. However, Solvay made no effort to seek an indication for Marinol® as a companion therapy to combat the side effects of HAART.

130. Solvay sales representatives who were timid or less-skilled were uncomfortable with promoting Marinol® for loss of appetite in cancer patients and for nausea and vomiting in HIV patients because they believed that it exposed the company or themselves to legal jeopardy. These representatives struggled to find a way to present data clearly labeled for patient types other than those treated by the physicians on whom the marketing representatives were instructed to call.

131. In 2005, Solvay continued to actively promote Marinol in the HIV and Oncology market places for the symptom management challenges of appetite, weight loss and nausea and vomiting.

132. The "Symptom Management Market" as Solvay understood it, consisted of FDA approved agents indicated for the treatment of appetite and weight loss as well for the reduction of nausea and vomiting. The patient population experiencing symptom management problems and targeted by Solvay for the "appropriate" use of Marinol® was HIV/AIDS, Cancer and long-term-care patients.

133. Marinol® was never FDA approved for the treatment of appetite. Indeed, the FDA had, no later than 1993, determined that the claim that Marinol® "restores the appetite" was "false and misleading."

134. A study published on July 20, 2006 in the Journal of Clinical Oncology found that Marinol® was **no more effective than placebo** in improving quality of life or mood and stimulating appetite in cancer patients. "Comparison of Orally Administered Cannabis Extract and Delta-9-Tetrahydrocannabinol in Treating Patients With Cancer-Related Anorexia-Cachexia Syndrome: A Multicenter, Phase III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial From the Cannabis-In-Cachexia-Study-Group, 24 J. Clin. Oncology 3394 (July 20, 2006).

135. No clinical study of cancer patients has

shown that Marinol® improves their appetite. Indeed, the only two legitimate studies have shown that it does not.

136. No clinical study of cancer patients has shown that Marinol® improves their quality of life.

137. No clinical study of cancer patients has shown that Marinol® improves their mood.

138. Notwithstanding the complete absence of scientific basis for the claim that Marinol® improves appetite in cancer patients, Solvay has since at least 2001 engaged in a massive and cynical campaign to train those involved in selling Marinol to convince those involved in providing care to cancer patients that it does.

139. By way of example, training materials distributed to Solvay sales representatives with responsibility to sell Marinol®, including Relators, instructed them to focus their marketing efforts on Oncology Nurses, and to "[s]ell role for Marinol® for all the product can do—antiemetic; appetite; pain relief; anxiety relief." Sales representatives were trained how to make false representations concerning the safety and efficacy of Marinol® for off-label uses to stimulate the appetite of cancer patients and others

who were not suffering from AIDS wasting accompanied by weight loss.

140. In order to achieve its lofty off-label goals for Marinol®, Solvay conducted national sales meetings and regional and district sales meetings designed specifically for the purpose of training representatives, including Relators, on off-label sales and marketing practices, and required them to implement such practices.

141. Sales representatives were instructed to distribute studies, abstracts, reviews, and Continuing Medical Education (CME) monographs regarding off-label uses, most of which were published or funded by Solvay.

142. Sales representatives were expected to plan multiple "educational" programs which were designed solely for the purpose of off-label selling.

143. For a sales meeting prep assignment during 2001, trainees were sent a handout entitled "Marinol® Paired Practice," which gave instructions on detailing Marinol® for appetite stimulation. They were instructed to use the handout to prepare themselves for detailing Marinol® for appetite stimulation to oncologists as well as HIV/AIDS

treating physicians.

144. Relator Hutto attended initial sales training during July or August of 2001, called "Basic Training One." Training at this time was strictly limited to Marinol's® FDA-approved indications. During the next several months with Solvay, however, Relator Hutto was trained on techniques in selling Marinol® to oncologists for appetite stimulation. Under the guise of detailing it as an antiemetic, he was instructed to mention its efficacy in appetite stimulation for cancer patients. If asked about Solvay's lack of indication for such use, he was instructed to say that Solvay has the same indication as Megace,® and so, if physicians felt comfortable using Megace® off-label, they should also feel comfortable using Marinol® off-label.

145. In late 2001 or early 2002, Relator Hutto attended "Basic Training Two." Off-label uses were prominently discussed in a PowerPoint presentation on Marinol® Marketing for 2002 led by a Solvay sales trainer. Numerous slides were presented on how sales representatives could grow Marinol® in the off-label appetite stimulation oncology market.

146. Defendants long have known that Megace® is more effective than Marinol® in improving

the appetites of cancer patients.

147. Defendants have long known that off-label use of Megace® for treatment of appetite loss in oncology patients is properly reimbursable by Medicaid because, unlike Marinol®, such use is supported by approved compendium listings.

148. Nevertheless, Solvay has actively trained its sales representatives, including Relators, to represent to Oncologists and Oncology Nurses the falsehood that Marinol® is better than Megace®.

149. Relator Hopper received an e-mail message from his District Manager on or about October 24, 2002, captioned "Field contact report," setting out the district manager's observations regarding a "ride along" when she went into the field with Mr. Hopper. She praised Mr. Hopper for "doing an exceptional job doing quick 1 minute liners about why Marinol is better than Megace" for appetite stimulation. She also exhorted Mr. Hopper to train other representatives on the purported differences between Megace® and Marinol®.

150. In 2003, sales representatives, including Relators, were distributed a "Success Story" in which a sales representative reported that she used "the

trusty Roly Poly clock" to remind oncologists of the supposed "appetite" benefits of Marinol®: "I commented, once again, 'It is time for your patients to have an appetite.' Corny, but I hope that this will help him to remember."

151. The "trusty Roly Poly clock" was a gift which defendants' sales representatives were directed to pass out to "your physicians" in "top offices." According to marketing materials disseminated to sales representatives, "[t]his unique capsule-shaped alarm clock will help you to continue to brand your offices, and remind your physicians that in 2003 it's 'MARINOL® Time'! You will be receiving approximately 75 clocks to be used in your top offices. Focus on those MARINOL® CPD 7–10s for this limited premium item."

152. The sales representative also reported that she had advised an oncologist who prescribed Compazine® that he should add Marinol® in combination therapy in order to achieve a "synergistic effect." As a result of her sales pitch, the doctor "indicated he would now also think of Marinol for the patients he sends home on Compazine. Yea!"

153. Marinol® has no indication or compendium support for use as combination therapy

with Compazine® or any other drug.

154. Defendants include, in their "double sunrise" marketing materials, a chart entitled "Additive/synergistic antiemetic effects with prochlorperazine," which is Compazine®. The graphic is part of a chart included in a 1991 study, Lane, *et al.*, "Dronabinal and Prochlorperazine in Combination for Treatment of Cancer Chemotherapy-Induced Nausea and Vomiting," 6 *J. Pain & Symptom Mgmt.* 352 (1991).

155. The study was funded by Roxane and Defendant UNIMED, and two of the study's authors were employed by them.

156. The partial chart reproduced by Defendants shows that when patients took Marinol® and Compazine® together, episodes of nausea and vomiting lasted a shorter time than when either drug was taken alone.

157. Although Defendants include the length-of-episode information from the Lane study in their marketing materials, those materials omit the fact that almost two-thirds of patients taking Marinol®, and more than half of those taking the combination, experienced neurologic or psychotropic side

effects—as compared with 29% of those receiving Compazine® alone.

158. Ten of 17 (59%) patients taking just Marinol® withdrew from the study due to adverse side effects or insufficient therapeutic effects, as opposed to two of 20 (10%) of those taking just Compazine®.

159. Defendants' Marketing materials discussing the Lane study tout an illegal off-label use of Marinol® in an unbalanced recitation of the study's findings.

160. Sales Representatives were trained and instructed to represent to physicians and other health care professionals that Megace® worked by adding weight mainly as fat rather than lean body mass. They were encouraged to represent that Marinol® is better than Megace® because it does not "add fat and water or affect libido."

161. Solvay knew that there was no credible evidence that the claims about Marinol® were true.

162. Solvay knew that there was no published literature comparing the relative effectiveness of the two drugs.

163. Results of a study by Dr. Jeffrey Abrams were published in 2003. The study showed that in those HIV patients who took Marinol® and gained weight, the weight was fat mass.

164. Relators were ordered not to discuss the Abrams data because "the perception with physicians is that Marinol® promotes a lean body mass weight gain and, Megace®, while achieving weight gain, is only in fat mass."

165. Relators were consistently instructed to continue insinuating, and representing, to physicians that patients—including cancer patients—who were prescribed Marinol® would gain lean body mass.

166. Though there has never been any evidence to support the claim, as late as 2005, Solvay continued to declare that Marinol added weight that was "lean body mass" while Megace added weight only by way of fat and water retention.

167. Marinol® sales representatives were expressly trained to represent to Oncologists and Oncology Nurses that there is a particular dosage of Marinol® which is best for appetite stimulation as compared with vomiting. This statement has no basis in science.

168. Defendants were made expressly aware by the FDA that it is illegal for them to make false statements in comparing Marinol® to other drugs, yet integrated such comparisons into the marketing programs imposed on their sales representatives, including Relators.

C. Off-Label Marketing Scheme Relating to Physicians Caring for Patients in Long-Term Care

169. Beginning no later than 2001, Solvay began attempting to induce physicians to prescribe Marinol® for use in patients in long term care.

170. Solvay sought to convince health care providers that cannabinoids were appropriately used in appetite stimulation, and sought to convince them that Marinol® should be considered standard therapy in the treatment of cancer, HIV/AIDS, and Long Term Care.

171. Solvay spent large sums of money to accomplish these goals.

172. Solvay knew that physicians with Marinol® experience believed that it was unsuitable for elderly patients because of its psychoactive effects.

173. There is no credible evidence or compendium support indicating that Marinol® is effective as an appetite stimulant to treat the long-term care population.

174. No clinical studies support the proposition that Marinol® is effective as an appetite stimulant to treat the long-term care population.

175. Marinol's® FDA-approved label warns specifically against using Marinol® in the elderly due to potential central nervous system (defined by Marinol's® label to include "feeling high, dizziness, confusion, and somnolence") and other psychomimetic side-effects. Specifically, the labeling states, "Marinol®" capsules should be used with caution in elderly patients because they may be more sensitive to the neurological, psychoactive, and postural hypotensive effects of the drug."

176. The label also provides that with respect to geriatric patients who have conditions within the FDA-approved indications for Marinol®, the drug should be administered at the low end of the dosing range to take into account "the greater frequency of falls, decreased hepatic, renal, or cardiac function, increased sensitivity to psychoactive effects and of concomitant disease or other drug therapy."

177. In 2002 Solvay began a vigorous attempt to expand Marinol's use in the long-term-care market.

178. Solvay sought to gain access to pharmacies and long-term care facilities with the "multiple benefits with a single agent" sales pitch.

179. Solvay sought to convince these and others of Solvay's claims that Marinol® was an effective appetite stimulant, antiemetic, and mood-enhancer.

180. Solvay wanted to steal market share from Megace®, which is the gold-standard appetite stimulant used in LTC settings.

181. Relator Hopper's 2002 Performance Evaluation noted as a key point under "Innovation" that he "[w]orked to develop Marinol® mkt. share by focusing on LTC pharmacies and developing sales strategies for these markets." It also notes that he "[c]ompleted inservice to LTC pharmacy that benefitted other territory within district" and "[w]orked with DM [District Manager] to develop and promote LTC pharmacy potential within District. Targeted two top LTC accounts and completed two inservices."

182. There is no credible scientific evidence that Marinol® is safe and effective as an appetite stimulant in Long Term Care patients.

183. Solvay has no FDA approval for use as an appetite stimulant in Long Term Care patients.

184. Solvay was aware that studies showed Megace® to have superior efficacy to Marinol®.

185. An open-label study of Marinol® in Alzheimer's patients showed changes in mental status such as agitation, somnolence and dizziness. Eight patients experienced one or more falls while on treatment. These two points raise concerns that elderly patients, especially those whose mental status may already be compromised or who are at risk for falls, should be administered Marinol® with caution.

186. Solvay relies on this study for the proposition that Marinol® is appropriate for use in an elderly population. This reliance is particularly egregious given that the study actually confirmed the findings which led to the FDA's insistence, in 1985, upon labeling language highlighting the risk of disturbing psychometric reactions in Marinol® recipients.

187. Solvay knew when it launched its long-term care off-label marketing push that Marinol® posed significant risks to the health and safety of elderly patients, including those elderly patients who constitute the overwhelming majority of long-term care patients.

188. Availability of Medicaid reimbursement was a critical element of Defendants' push into the Long Term Care market.

189. Solvay knew that the long-term care market was 70% paid-for by Medicaid dollars. In 2004, approximately 30% of Marinol® prescriptions—more than 35,000 prescriptions—were written in the long-term care market.

190. Notwithstanding the clinical and scientific evidence, Solvay asserted that Marinol® was a safe and effective appetite stimulant; was safer than Megace®; and had proven efficacy in the geriatric population for weight gain, appetite stimulation, reduced agitation, and enhanced mood.

191. These claims were all false.

192. Solvay's main thrust for Marinol® was to nurture the HIV/AIDS business and further penetrate

oncology and long-term care—the two off-label and scientifically-unsupported sectors of the business.

D. Kickbacks to Health Care Providers In Exchange for Provision of Off-Label Marketing Services

193. Solvay illegally promoted the off-label uses of Marinol® through offers and payments of remuneration in violation of the Anti-Kickback Statute.

194. Solvay paid physicians and other healthcare providers for participation in such programs as preceptorships, speaker training, speaker events and dinners, and travel summits. These programs were implemented to induce physicians to write prescriptions for Marinol.

195. The "preceptorship" payments paid to physicians and healthcare providers were ostensibly to allow a sales representative to "shadow" the physician. Sales representatives were expected to conduct a set number of preceptorships per year. Preceptorships were simply paid-for sales-pitch opportunities.

196. Relator Hopper's 2002 performance

evaluation noted as an accomplishment under "Strategic Thinking" that he "[t]argeted highest potential Doc's with DART. Completed preceptorships with top targets." Under "Continuous Learning," "[c]ompleted 10 preceptorships, was able to gain insight to oncology practice."

197. "Preceptorships" are a sales tactic driven from Solvay's corporate offices in order to develop personal relationships between sales reps and physicians and nurses.

198. Solvay recognized that physicians permitted preceptorships because they were paid to permit access.

199. Relators' District Manager gave a presentation to her sales staff, including Relators, in or about February 2002. She described preceptorships as a "Marinol® Key Tactic." The District Manager indicated that the sales representatives were to "Target top 10 Marinol Writers and top 15 Megace writers" in their territories. "Ideally, called on once a week. Minimum is every other week." She also instructed that "[m]arketing $ can only be spent on these physicians."

200. Relators were advised by their District

Manager that the sales territory which included Kentucky, Georgia, Louisiana, Florida, Mississippi, Alabama and Tennessee was budgeted for and had completed 100 preceptorships.

201. Solvay sales representatives commonly used preceptorships to try to persuade doctors to write off-label prescriptions, telling them that Marinol® would help with a cancer patient's loss of appetite.

202. Solvay also paid physicians and nurses to attend speaker "training sessions," and then paid the speakers to speak at dinner programs and other events. These events were used by Solvay as a way to induce physicians to prescribe Marinol, mainly for off-label uses. Recruitment of physicians who were willing to perform peer-selling was a main component of implementing Marinol's off-label strategies.

203. In May 2003, a one-day speaker training meeting titled "Prioritizing Patient Care: Aspects of System Management," was held at the New York Palace in New York City. It was attended by oncologists and HIV/AIDS specialists–eight "faculty" members and twenty "participants" who were paid by Solvay to speak and/or attend. In addition, roundtrip air travel, overnight hotel accommodations for two

nights, and meals were provided to all trainers and participants. Also in attendance were Solvay's Senior Product Manager, Associate Product Manager, Business Director and six Regional Marketing Managers.

204. At the training session, the participants received training on the use of a multimedia slide show and case study program, which included program materials discussing the HIV patient and cannabinoids.

205. The oncology program included information regarding the oncology patient and cannabinoids and treatment options for antiemetics and appetite stimulants.

206. The case study topics presented included the fact that weight loss can be treated with dronabinol and that severe anorexia and weight loss are common with progressive cancer

207. In June 2002 a "Marinol® Clinical Educators Panel Meeting" was held in Atlanta, Georgia. It was attended by Solvay management personnel and eleven physicians who were HIV/AIDS specialists or oncologists, many of whom were also employed by Solvay as speakers/consultants. It

consisted of a dinner program in the evening, followed the next day by a panel meeting at which the stated objectives were to (a) provide the latest key clinical information regarding Marinol®; (b) provide future research direction for Marinol®; (c) provide future market positioning for Marinol®; and (d) receive feedback and advice from the attendees concerning clinical experience, medical education, etc. Each physician attendee was provided with an honorarium, plus business class airfare, hotel accommodations, meals, ground transportation and incidental expenses.

208. On April 4, 2003, Dr. [251-01] spoke to the Connecticut Chapter of American Society of Consultant Pharmacists at the Foxwoods Casino in Uncasville, CT. His presentation was titled "Nutrition and Aging" and a check to cover his fee and travel expenses was sent to the Society.

209. Solvay paid Dr. [252-01] a fee and travel expenses to make a one-day trip to a Scientific Poster Presentation in San Antonio, Texas on November 13, 2003. The title of Dr. [252-01]'s poster/presentation was "Open-Label Study of Dronabinol in the Treatment of Refractory Agitation in Alzheimer's Disease: A Pilot Study." The audience consisted of consultant pharmacists.

210. Ms. [253-01], an oncology nurse practitioner, was a paid speaker for Marinol®. From July 2001 through October 2002 she was the speaker at 20 Solvay-sponsored and funded events attended by oncology nurses. The nurses were compensated for attending. All of the events were classified as promotional meetings and many were dinner meetings with the title of "Clinical Applications of Dronabinol." At one such event, the product focus was listed as "Dual Indication." At another it was to "increase awareness of the benefits of administration of Marinol® to patients for both indications" and to "show acceptance of Marinol® by a well known peer." At another, the product focus was "Marinol®—nutrition for oncology," and the positive business effect as stated by the Solvay sales representative arranging it was to "[i]ncrease awareness and number of scripts for Marinol®."

211. From January 2003 through November 2003, Ms. [253-01] spoke on behalf of Solvay at six Oncology Nurse Society chapter meetings, labeled as scientific/educational meetings. She was paid fees by Solvay for each meeting.

212. Ms. [253-01]'s Solvay-paid speaking engagements included favorable dronabinol clinical information and case presentations, including

dronabinol's supposed off-label utility as an appetite stimulant in the oncology patient.

213. Defendants knowingly and willfully offered and paid cash and in-kind remuneration to physicians and others with the purpose of inducing them to prescribe Marinol® for off-label uses.

214. Remuneration offered and paid physicians was not consistent with fair market value in arms-length transactions.

215. Remuneration offered and paid physicians was determined in a manner that took into account the volume or value of business generated by the physician's prescriptions for off-label uses of Marinol®, which were paid in a significant part by federal health care programs.

216. Remuneration offered and paid physicians was not in exchange for legitimate services actually rendered.

217. Rather, the remuneration was overpayment for nominal or no services and was actually intended to induce the physician to prescribe Marinol® for non-reimbursable, off-label uses.

218. Defendants were aware that their actions did in fact result in the prescribing of Marinol® for off-label uses and that those prescriptions were paid for in significant part by federal health care programs.

219. Defendants were aware that the payment of kickbacks to induce the ordering of drugs paid in whole or part by federal health care programs was in violation of the Anti-Kickback Act.

220. Defendants were aware that violators of the Anti-Kickback Act were ineligible for payment under any federal health care program.

221. Notwithstanding this fact, Defendants intentionally and purposefully offered and paid illegal kickbacks to physicians. Defendants knew that the foreseeable consequence of these actions was the submission of false claims to federal health care programs by violators of the Anti-Kickback Act. Nevertheless, Defendants intentionally and purposefully implemented a strategy to cause the submission of increased false claims for the off-label use of Marinol®.

E. False Internet Marketing

222. Defendants have extensively used the Internet to make false marketing claims about Marinol®.

223. In early 2002, Solvay began to use and continues to use third party oncology treatment web sites like CancerConsultants.com to provide this information.

224. Defendants have vigorously implemented this strategy. They have paid CancerConsultants.com, and in return, CancerConsultants.com has engaged in off-label advertising for Marinol®.

225. Numerous websites of cancer hospitals and oncology practices include documents ostensibly written by "Cancerconsultants.com" which provide information about the single study that led to approval of Marinol® for "anorexia accompanied by weight loss in AIDS patients." These websites present the results of this study without disclosing that it did not involve cancer patients or that FDA approval for the anorexia indication applies only to AIDS patients.

226. Defendants' purpose in connection with these website placements is to induce cancer patients to request Marinol® for appetite problems.

227. Such websites, all with identical content, include:

University of Florida Shands Cancer Center, available online at http://ufscc.ufl.edu/Patient/content.aspx?section=cancertreatment&id=23155

Tennessee Oncology, a large oncology practice, http://tnoncology.com/lc-poor-appetite.html

South Texas Oncology Hematology, http://www.stoh.com/content.aspx?section=cancertreatment&id=987

NCH Healthcare System Regional Cancer Institute, http://cancer.nchmd.org/treatment.aspx?id=23155

Medical Oncology & Hematology P.C., a large Connecticut practice, http://mohmd.com/Content.aspx?Section=cancertreatment&DocumentID=987

Connecticut Oncology & Hematology,

http://www.connonc.com/content.aspx?section=cancertreatment&id=987

CancerConsultants.com itself, an online-only "information" website, at http://patient.cancerconsultants.com/SideEffects.aspx?TierId=1090&DocumentId=23155

Caring4Cancer.com, an "information" website, at http://cancer.caring4health.com/Mesothelioma/Articles/Weight-Loss-and-Anorexia_A303424_C316140.aspx

228. In or about 2006 and 2007, Defendants sponsored ads on, at least, the website for Air America Radio stating "Marinol® (dronabinol) Get Help for HIV/AIDS Weight Loss and Chemo Related Nausea and Vomiting Marinol®.com." Clicking on the advertisement takes the viewer to http://www.Marinol.com, the "official" website for Marinol® operated by defendants. On information and belief, similar advertisements have been placed by defendants on numerous other web sites.

229. Defendants' campaign to market Marinol® primarily for off-label use continued without cessation

until at least early 2006, and on information and belief continues as of the filing of this Second Amended Complaint.

F. Defendants Caused Submission of False Claims to Medicaid and Other Federally-Funded Health Programs

230. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily-established share of "the total amount expended ... as medical assistance under the State plan ..." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

231. The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program

(Form CMS-64) is the accounting statement which states, in accordance with 42 C.F.R. § 430.30(c), must submit each quarter under title XIX of the Social Security Act (the Act). It shows the states' actual expenditures for the quarter being reported and previous fiscal years, the recoupment made or refunds received, and income earned on grant funds. These amounts, including the amounts paid for prescription drugs, such as Marinol®, have a direct effect on the amount of FFP paid by the federal government.

232. Although states may, under federal law, pay for any drug for any indication, they must do so without FFP if the drug, as prescribed, is not for a medically acceptable use. FFP is available to states only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). "Covered outpatient drugs" do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id., § 1396r-8(k)(3). A medically-accepted indication is defined as a use "which is approved under the Federal Food Drug and Cosmetic Act" ("FDCA") or which is "supported by one or more citations included or approved for inclusion" in specified drug compendia. Id. § 1396r-8(k)(6). 42 U.S.C. § 1396r-8(g)(1)(B)(i) These are American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; and the DRUGDEX Information System

("the Drug Compendia").

233. Solvay consciously and closely focused on the extent to which Medicaid paid for Marinol®. For example, in 2003, Solvay knew that Medicaid payments for Marinol® accounted for a relatively large percent of total payments at 25.6%, compared to a market average Medicaid payment of 11%. The Medicaid portion of payments is relatively higher for Marinol® compared to its competitors, Oxandrin and Megace® OS.

234. Solvay predicated its illegal off-label marketing campaigns for Marinol® on the availability of "universal reimbursement"—the premise that because it could be prescribed for *some* Medicaid-reimbursable conditions (that is, AIDS anorexia with weight loss, and refractory CINV), any claims submitted for other purposes would be paid. Defendants thus not only knew, but affirmatively predicated their off-label marketing plan on their knowledge that false claims for off-label uses would be submitted and would be reimbursed.

235. Defendants predicted that Medicaid would account for 33% of Marinol® sales in 2003.

236. Solvay tracked Medicaid

reimbursements, and, for example, identified a high volume of Medicaid prescriptions for Appetite Stimulation resulting from inclusion of its drug on the Texas Medicaid formulary.

237. Medicaid payments for Marinol® during the years of defendants' illegal off-label marketing campaigns were:

Year	Medicaid Reimbursement
1999	$15,716,311.24
2000	$21,633,884.30
2001	$17,309,950.06
2002	$36,197,808.90
2003	$51,210,009.08
2004	$62,397,145.71
2005	$69,927,180.27

238. The majority of the Medicaid claims for Marinol® were made as a result of prescriptions written for patients who were prescribed Marinol® for the off-label treatment of cancer cachexia; for the off-label treatment of loss of appetite in long-term-care patients; for the off-label treatment of appetite issues in HAART patients; and for other off-label uses.

239. When pharmacies, physicians and other healthcare providers submitted claims based upon a physician's prescription for Marinol® to treat cancer cachexia, to treat HAART patients, and to treat long-term care patients, the claims they submitted were

false because Marinol® was not medically indicated and necessary, and these off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(i). In fact, neither the United States Pharmacopeia nor the American Hospital Formulary Service lists Marinol® for the off-label uses.

240. The DRUGDEX listing expressly indicates that Marinol® is ***ineffective*** as a treatment for cancer-related anorexia. The listing is reproduced below.

> ANOREXIA - CANCER-RELATED
> 1. OVERVIEW:
> FDA APPROVAL: Adult, no; pediatric, no
> EFFICACY: Adult, ***ineffective***
> DOCUMENTATION: Adult, good
> 2. SUMMARY: - Dronabinol alone or combined with megestrol was no more effective than megestrol alone in patients with advanced cancer
>
> 3. ADULT:
>
> a. **In a double-blind, multi-center**

trial, DRONABINOL was found to provide significantly less amelioration of anorexia than MEGESTROL in patients with advanced cancer experiencing anorexia; and dronabinol in combination with megestrol did not confer additional benefit over megestrol alone. Enrollees had incurable malignancies (other than brain, breast, ovarian, or endometrial cancer), with a life expectancy of 3 months or more and a performance status of 0 to 2 on the Eastern Cooperative Oncology Group scale. Eligible patients also had recent weight loss of at least 5 pounds and/or physician-estimated caloric intake of less than 20 calories/kilogram; all believed that loss of appetite or weight loss was a problem for them. Subjects were randomized to 1 of 3 protocols: megestrol acetate liquid suspension 800 milligrams (mg) per day orally (n=159), dronabinol capsules 2.5

mg orally twice daily (n=152), or both (n=158). Median duration of therapy varied from 57 to 80 days across the 3 groups. On patient questionnaires, 75% of those receiving megestrol reported increased appetite compared with 49% of those receiving dronabinol (p=0.0001); 66% in the combination group reported increased appetite (p=0.17 versus megestrol alone). A 10% or greater weight gain occurred in 11% of those on megestrol, 3% of those on dronabinol (p=0.02 vs megestrol), and 8% of those on both medications (p=0.43 vs megestrol alone). Scores on the Functional Assessment of Anorexia/Cachexia Therapy instrument (emphasizing anorexia-related questions) were significantly better for the megestrol-treated patients (p=0.002). Of male patients, 18% who received megestrol experienced impotence compared with 4% of those receiving dronabinol (p=0.002) (Jatoi et al,

2002).

241. Claims for Marinol® prescribed for these off-label uses were therefore not eligible for federal financial participation, and were not covered by state Medicaid programs

242. Solvay was aware that off-label uses of Marinol® were not covered and payable by Medicaid. Solvay was aware that the natural and probable consequence of its promotion of off-label uses of Marinol® was that health care providers would submit claims for payment to Medicaid and other government payors for the off-label use. Notwithstanding this fact, Solvay illegally promoted off-label uses of Marinol®. Solvay was aware that its illegal promotion did in fact result in false claims to Medicaid and other government payors for the off-label use. Solvay was aware that its promotion activities were a substantial causal factor in producing the claim.

243. As a result of Solvay's actions, healthcare providers submitted Pharmacy Claim Forms and CMS-1500 Forms to state Medicaid programs, and the states submitted Form CMS-64, all claiming reimbursement for Marinol® for such off-label use. Solvay caused the submission of these false claims.

244. The overwhelming majority of the claims for off-label prescribing of Marinol® for cancer cachexia patients, long-term-care patients, and HAART patients was the direct and proximate result of unlawful off-label marketing efforts by defendants.

245. During the period 2001-04, the following cancer physicians, each of whom was called upon by Relator Hopper and to each of whom Solvay, through Relator Hopper, advocated the off-label prescribing of Marinol®, wrote at least the following numbers of Marinol® prescriptions, all or most of which were for off-label uses.

Last	First	Specialty	Location	Total
287-01		Hematology	Birmin, AL	5
287-02		Oncology	Birmin, AL	20
287-03		Oncology	Birmin, AL	21
287-04		Oncology	Birmin, AL	22
287-05		Oncology	Biloxi, MS	23
287-06		Oncology	Baton Rouge, LA	26
287-07		Oncology	Beaumont, TX	29
287-08		Oncology	Birmin, AL	33
287-09		Oncology	Biloxi, MS	36
287-10		Oncology	Anniston, AL	40
287-11		Oncology	Birmin, AL	42
287-12		Hematology	Alabaster,AL	44
287-13		Oncology	Birmin, AL	67
			Total	408

246. This group of physicians wrote no prescriptions for Marinol® in 2000. In each successive

year, their aggregate prescribing pattern increased with defendants' off-label marketing efforts. The group wrote 29 Marinol® prescriptions in 2001; 103 in 2002; 134 in 2003; and 142 in 2004.

247. Each of the above-named physicians was "targeted" by defendants for off-label marketing activities by Relator Hopper because defendants purchased data showing that these physicians prescribed Megace®.

248. It is impossible to determine at this juncture which of the 408 patients for whom these physicians prescribed Marinol® were eligible for Medicaid reimbursement. However, defendants' marketing documents recognize that at least 10% of cancer patients are insured by Medicaid.

249. Nationwide, physicians wrote the following numbers of Marinol® prescriptions:

Year	Prescriptions
2000	10,367
2001	16,713
2002	64,855
2003	139,615
2004	124,208

250. Defendants, through their illegal off-label

marketing campaigns, knowingly caused the submission of hundreds of thousands of false Medicaid claims which would not have been reimbursed had the responsible agencies known the circumstances under which such prescriptions were written.

G. Claims for Off-label Marinol® Did Not Qualify for Medicare Coverage

251. Medicare Part A is funded primarily by a federal payroll tax, premiums paid by Medicare beneficiaries and appropriations from Congress. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e - 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting.

252. Medicare Part B is optional to beneficiaries and covers some health care benefits not provided by Medicare Part A. Medicare Part B is funded by appropriations from Congress and premiums paid by Medicare beneficiaries who choose to participate in the program. 42 U.S.C. §§1395j - 42 U.S.C. §§1 395w-4. Medicare Part B pays for some types of prescription drugs that are not administered

in a hospital setting. 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517. These typically include drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics (drugs which control the side effects caused by chemotherapy), and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517.

253. On January 1, 2006, Part D of the Medicare program began providing drug coverage for all beneficiaries. The drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k).

254. Specific coverage rules apply to anti-cancer drugs. 42 U.S.C. 1395x(t) and Medicare Carriers Manual 2049.4C. Section 2049.4C is reproduced here, in part:

> Unlabeled Use For Anti-Cancer Drugs.--Effective January 1, 1994, unlabeled uses of FDA approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen for a medically accepted indication are

evaluated under the conditions described in this paragraph. A regimen is a combination of anti-cancer agents which has been clinically recognized for the treatment of a specific type of cancer.

* * *

For purposes of this provision, a cancer treatment regimen includes drugs used to treat toxicities or side effects of the cancer treatment regimen when the drug is administered incident to a chemotherapy treatment. Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the use is not listed as "not indicated" in any of the three compendia. (See note at the end of this subsection.)

1. American Hospital Formulary Service Drug Information--Drug monographs are arranged in alphabetical order within therapeutic classifications. Within the text of the monograph, information concerning indications is provided,

including both labeled and unlabeled uses. Unlabeled uses are identified with daggers. The text must be analyzed to make a determination whether a particular use is supported.

2. American Medical Association Drug Evaluations.*[no longer published. As of 1996, merged with USP]*

* * *

3. United States Pharmacopoeia Drug Information (USPDI)— Monographs are arranged in alphabetic order by generic or family name. Indications for use appear as accepted, unaccepted, or insufficient data. An indication is considered to be a medically accepted use only if the indication is listed as accepted. Unlabeled uses are identified with brackets.

* * *

4. A Use Supported by Clinical Research That Appears in Peer Reviewed Medical Literature--This applies only when an

unlabeled use does not appear in any of the compendia or is listed as insufficient data or investigational. If an unlabeled use of a drug meets these criteria, contact the compendia to see if a report regarding this use is forthcoming. If a report is forthcoming, use this information as a basis for your decision making. The compendium process for making decisions concerning unlabeled uses is very thorough and continuously updated. Peer reviewed medical literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

* * *

NOTE: If a use is identified as not indicated by HCFA or the FDA or if a use

> is specifically identified as not indicated in one or more of the three compendia mentioned or if you determine based on peer reviewed medical literature that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered.

255. Claims for Marinol® when submitted to Medicare for these uses are not covered. The use of Marinol® for cancer-related anorexia is listed as ineffective (not indicated) in one of the three drug compendia, DRUGDEX, and therefore is automatically not covered.

256. The off-label uses discussed herein are not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective" for such uses.

257. Defendants were aware that off-label uses of Marinol® were not covered and payable by Medicare, and that the natural and probable consequence of its promotion of off-label uses of Marinol® was that health care providers would submit

or cause submission of claims for payment to Medicare and other government payors for the off-label use.

258. Notwithstanding this knowledge, Solvay illegally promoted off-label uses of Marinol®.

259. Solvay was aware that its illegal promotion did in fact result in false claims to Medicare and other government payors for the off-label use. Solvay was aware that its promotion activities were a substantial factor in producing the claim.

260. False claims to Medicare for off-label prescribing of Marinol® for cancer cachexia patients, long-term-care patients, and HAART patients were the direct and proximate result of unlawful off-label marketing efforts by Defendants. As a result of these efforts, Defendants caused the submission of these false claims.

H. Claims for Off-label Marinol® Did not Qualify for Reimbursement Under Other Federal Health Care Programs

1. CHAMPUS/TRICARE, CHAMPVA and the FEHBP

261. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

262. The off-label uses of Marinol® promoted by Defendant were not eligible for reimbursement under any of the various federal health care programs. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

2. Direct Purchases By Federal Agencies

263. In addition to reimbursing drug purchases through Medicare, Medicaid, and other federal health care programs, the United States is a significant direct purchaser of prescription drugs through various federal programs. The United States paid money for Marinol® claims which were the result of defendants' unlawful off-label marketing plan. For instance, the Federal Employee Health Benefit

Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

3. Programs Administered by the Department of Veterans Affairs

264. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

4. Programs Administered By The Department of Defense

265. The Department of Defense ("DOD") provides prescription drug coverage to approximately eight million active duty personnel, retirees, and their families through three points of service: military treatment facility outpatient pharmacies, TRICARE managed care contractor retail pharmacies, and the National Mail Order Pharmacy Program. DOD negotiates independent contracts to purchase the majority of the prescription drugs provided through these programs.

266. Solvay was aware that off-label uses of Marinol® were not covered and were not legally payable by any of these programs.

267. Solvay was aware that the natural and probable consequence of its promotion of off-label uses of Marinol® was that health care providers would submit claims for payment to these and other government payors for the off-label use.

268. Notwithstanding this knowledge, Solvay illegally, vigorously, and without any thought to the possible negative health effects to which it subjected patients, promoted off-label uses of Marinol®. Solvay was aware that its illegal promotion did in fact result in false claims to these and other government payors for the off-label use. Solvay was aware that its promotion activities were a substantial factor in producing the claim.

269. False claims to these government programs for off-label prescribing of Marinol® for cancer cachexia patients, long-term-care patients, and HAART patients were the direct and proximate result of unlawful off-label marketing efforts by Defendants. Defendants caused the submission of these claims.

IV. CLAIMS FOR RELIEF

COUNT I—FALSE CLAIMS ACT

270. Relators reallege and incorporate by reference paragraphs 1-269 as though fully set forth herein.

271. This is a claim by Relators, on behalf of The United States, for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. From on or about January 2000 through present, in the Middle District of Florida and elsewhere throughout the United States, Defendants have knowingly and willfully violated the False Claims Act by causing false claims to be submitted against federal funds by engaging in a massive off-label marketing campaign for Marinol®.

272. Defendants knowingly made, used, or caused to be made or used false records and/or statements to get false or fraudulent claims paid or approved by the Government, in violation of subsection 3729(a)(2). Each prescription that was written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement.

273. Defendants have knowingly caused pharmacies and other healthcare providers to submit Pharmacy, CMS-1500, and other claim forms for payment for Marinol®, knowing that such false claims would be submitted to state Medicaid programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing prescriptions for non-covered uses and therefore false claims. By virtue of the acts described in this Complaint, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. §3729(a)(1) and 31 U.S.C. §3729(a)(2).

274. Defendants have violated 31 U.S.C. §3729(a)(2) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Marinol®, were paid for in compliance with federal law. States submitted false claims to the United States Government because *when Marinol® was prescribed off-label, it was not a "covered outpatient drug,"* yet states sought reimbursement from the United States Government for all Marinol® expenditures.

275. Defendants caused false claims to be submitted for Marinol®, resulting in Government Program reimbursement to healthcare providers in the millions of dollars, in violation of the False Claims Act, 31 U.S.C. §3729 et. seq. and the Anti-Kickback Act 42 U.S.C. §1320a-7b(b)(2)(A).

276. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

WHEREFORE, Relators respectfully request this Court enter judgment against SOLVAY, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq. provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendants caused to be presented to the

Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relators necessarily incurred in bringing and pressing this case;

(d) That the Relators be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT II—ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT

Relators repeat and reallege each allegation contained in paragraphs 1 through 269 above as if fully set forth herein.

277. This is a *qui tam* action brought by Relators on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

278. 740 ILCS 175/3(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

279. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in

kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

280. Defendants violated 305 ILCS 5/8A-3(b) by engaging in the conduct described herein.

281. Defendants furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were eligible for reimbursement by the government-funded healthcare programs.

282. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

283. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and

belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

284. Had the State of Illinois known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

285. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

286. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, and have brought this action pursuant to 740 ILCS 175/3(b) on behalf of themselves and the State of Illinois.

287. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Defendants:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relators:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT III—CALIFORNIA FALSE CLAIMS ACT

288. Relators repeat and reallege each allegation contained in paragraphs 1 through 269 above as if fully set forth herein.

289. This is a *qui tam* action brought by Relators on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650

et seq.

290. Cal. Gov't Code § 12651(a) provides liability for any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof; a false claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
>
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.

> (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

291. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

292. Defendants violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the conduct described herein.

293. Defendants also violated Cal. Gov't Code § 12651(a) and knowingly caused thousands of false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650.1

and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct was eligible for reimbursement by the government funded healthcare programs.

294. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

295. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

296. Had the State of California known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded

healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

297. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

298. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint and have brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.

299. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Defendants:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;

(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relators:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relators incurred in connection with this action;

(3) An award of reasonable attorneys'

fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT IV—MASSACHUSETTS FALSE CLAIMS ACT

300. Relators repeat and reallege each allegation contained in paragraphs 1 through 269 above as if fully set forth herein.

301. This is a *qui tam* action brought by Relators on behalf of the State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) *et seq.*

302. Mass. Gen. Laws Ann. Chap. 12 § 5B provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or

approval of a claim by the commonwealth; or

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

303. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

304. Defendants violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the conduct described herein.

305. Defendants furthermore violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Ann. Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were eligible for reimbursement by the government-funded healthcare programs.

306. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

307. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection

with Defendants' conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Massachusetts.

308. Had the State of Massachusetts known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

309. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the State of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

310. Relators are private citizens with direct and independent knowledge of the allegations of this Complaint and have brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2) on behalf of themselves and the State of Massachusetts.

311. This Court is requested to accept pendent

jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Defendants:

To the State of Massachusetts:

(1) Three times the amount of actual damages which the State of Massachusetts has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Massachusetts;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relators:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, § 5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

DATED this 20th day of November, 2007.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2007, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a Notice of Electronic Filing.

/s/ Frederick M. Morgan, Jr.
Frederick M. Morgan, Jr.

OPPOSITION BRIEF

Supreme Court, U S
FILED
MAY 10 2010
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No. 09-1065

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA ex rel.
JAMES HOPPER AND COLIN HUTTO,
Petitioners,

v.

SOLVAY PHARMACEUTICALS, INC. and
UNIMED PHARMACEUTICALS, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

1. Whether this Court should grant certiorari review to determine whether Rule 9(b), Fed. R. Civ. P. requires identification of a specific false claim in order to plead a violation of the False Claims Act, 31 U.S.C. § 3729(a)(2), when the Eleventh Circuit declined to address that issue.

LIST OF PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

Petitioners James Hopper and Colin Hutto were the relators in the proceedings before the United States District Court for the Middle District of Florida, Tampa Division, and the appellants in the proceedings before the Eleventh Circuit Court of Appeals.

Respondents Solvay Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc. were the defendants in the proceedings before the United States District Court for the Middle District of Florida, Tampa Division, and the appellees in the proceedings before the Eleventh Circuit Court of Appeals.

Unimed Pharmaceuticals, Inc., now known as Unimed Pharmaceuticals, LLC, is a wholly-owned subsidiary of Solvay Pharmaceuticals, Inc., now known as Abbott Products Inc.

Solvay Pharmaceuticals, Inc., now known as Abbott Products Inc., was acquired by, and became an indirect and wholly-owned subsidiary of, Abbott Laboratories, which is publicly traded on the New York Stock Exchange.

Prior to its acquisition by Abbott Laboratories, Solvay Pharmaceuticals, Inc. was a wholly-owned subsidiary of Solvay Pharma U.S. Holdings, Inc. Solvay Pharma U.S. Holdings, Inc.'s parent company is Solvay S.A., which is publicly traded on the Euronext Brussels Exchange. Solvay S.A. remains an interested party

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IN THE

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No. 09-1065

UNITED STATES OF AMERICA ex rel.
JAMES HOPPER AND COLIN HUTTO,
Petitioners,

v.

SOLVAY PHARMACEUTICALS, INC. and
UNIMED PHARMACEUTICALS, INC.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

Respondents Unimed Pharmaceuticals, LLC and Solvay Pharmaceuticals, Inc., now known as Abbott Products Inc., (collectively referred to hereinafter as "Solvay") respectfully oppose the petition for writ of certiorari to review the judgment entered by the United States Court of Appeals for the Eleventh Circuit.

OPINIONS BELOW

The opinion of the Eleventh Circuit is reported at 588 F.3d 1318 (Pet. App. at A-35). The report and

recommendation of the magistrate judge (Pet. App. at A-3), which was adopted by the District Court (Pet. App. at A-32), is reported at 590 F Supp. 2d 1352

JURISDICTION

The Eleventh Circuit entered its judgment on December 4, 2009. Pursuant to Supreme Court Rule 13.1, Petitioners filed their petition for writ of certiorari on March 4, 2010. If the Court grants the petition, jurisdiction exists pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Rule 9(b), Fed. R. Civ. P. provides:

> In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

The False Claims Act, 31 U.S.C. § 3729, provides:

> **(a) Liability for certain acts.** – Any person who –
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government . . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not

> more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

COUNTER STATEMENT OF THE CASE

Petitioners seek certiorari to review the following question:

> Whether Rule 9(b), Fed. R. Civ. P. requires the identification of a specific false claim in order to plead a violation of the False Claims Act, 31 U.S.C. § 3729(a)(2).

Pet. at i

Petitioners fail to disclose that the question on which they seek review was not decided by the Eleventh Circuit. In fact, the Eleventh Circuit specifically declined to address that question:

> Whether the relators' Complaint alleges with particularity the payment of a false claim is a question we need not answer. Even if it did, the Complaint remains deficient because it fails to allege that the defendants *intended* for the government to rely on their false statements in deciding whether to pay a false claim.

United States ex rel. Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1330 (11th Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3531 (U.S. Mar. 4, 2010) (No. 09-1065), Pet. App. at A-59 (emphasis added) [1]

Petitioners do not seek certiorari to review the actual holding of the Eleventh Circuit, that Petitioners'

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[1] The Eleventh Circuit's decision is included in Petitioners' appendix. Further references to the Eleventh Circuit's decision will be to the appendix.

complaint was properly dismissed because it failed to allege the "intent" required under section (a)(2) [2]

Petitioners brought claims under sections (a)(1) and (a)(2) of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729(a)(1) and (a)(2). The district court found the complaint insufficient under both sections (a)(1) and (a)(2) because it failed to plead with particularity that a false claim was submitted to the government. Pet App. at A-18-29. On appeal, Petitioners urged that under either section (a)(1) or (a)(2), allegation of a specific false claim is not required if the complaint includes other indicia of reliability that a false claim was made. In addition, Petitioners urged for the first time that, under this Court's decision in *Allison Engine Co. v. United States ex rel Sanders*, 553 U.S. 662 (2008), section (a)(2) did not require proof that a false claim was presented to the government Respondents argued that Petitioners had waived their claim that *Allison Engine* warranted a different pleading standard for claims under section (a)(2) because they had not made the argument to the district court.[3] Brief of Appellees, Resp App. at 1a-5a.

The Eleventh Circuit affirmed the district court's dismissal of the complaint in its entirety. As the Eleventh Circuit noted, section (a)(1) imposes liability on a person who "knowingly presents, or causes to

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[2] Petitioners "respectfully assert" in a footnote to their Petition that the complaint does allege this intent requirement, but they do not suggest that the sufficiency of their allegation of intent warrants this Court's review. Pet at 13 n 3

[3] Respondents also argued that even if Petitioners had not waived their claim that *Allison Engine* warranted a different pleading standard for section (a)(2) claims, on the merits Petitioners' allegations still did not satisfy Rule 9(b)

be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). The court found Petitioners' complaint deficient under section (a)(1) because it alleged nothing specific to provide indicia of reliability that false claims were actually made to the government. Instead, it "piles inference upon inference to suggest that Solvay's marketing campaign influenced some unknown third parties to file false claims." Pet. App. at A-49-50. Petitioners have not sought this Court's review of the Eleventh Circuit's ruling on their claims under section (a)(1) of the FCA [4]

The Eleventh Circuit then addressed whether the complaint survived under section (a)(2). As applicable to this case, section (a)(2) imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." The court determined that under the now-superseded language of section (a)(2) and this Court's decision in *Allison Engine*, the statute required proof of two things: 1) that the alleged false statements ultimately led the government to pay amounts that it did not owe; and 2) that the defendants made a false record or statement "with the purpose of inducing payment of a false claim 'by the

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[4] In addition to the Question Presented, the body of the Petition makes clear that Petitioners are seeking review only of the Eleventh Circuit's ruling with regard to their claims under section (a)(2). *See* Pet. at 11 ("[T]he Second Amended Complaint alleged that respondents violated 31 U.S.C. § 3729(a)(2) ."), *see also id.* at 20 ("[T]he Court should clarify" Rule 9(b) "with respect to claims under (a)(2) ." arguing that the Court should rely on the First Circuit's "treatment of the (a)(2) issue.")

Government.'" Pet. App. at A-52-57, 59-61 (quoting *Allison Engine*, 553 U.S. 662, 128 S.Ct. at 2130).[5]

The Eleventh Circuit concluded that the first requirement – that the government actually paid a false claim – required that someone submitted false claims to the government. Pet. App. at A-56-58. The court declined to decide how specific a relator's pleadings would have to be to meet that requirement. Citing the First Circuit's analysis in *United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13 (1st Cir. 2009),[6] the court noted that the pleading standard under section (a)(2) might be more relaxed than under section (a)(1) and might be satisfied by "general allegations of improper government payments to third parties, supported by factual or statistical evidence to strengthen the inference of fraud, like those in the relators' Complaint . . So, in the appropriate case, we may consider whether the particularity requirements of Rule 9(b), as to the details of the alleged false claims at issue, are more

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[5] The Eleventh Circuit noted that in May 2009, the Fraud Enforcement and Recovery Act, Pub L No 111-21, § 4, 123 Stat 1617, 1621 ("FERA"), amended the FCA and legislatively overruled the intent requirement set out in *Allison Engine*. The court analyzed the retroactivity provisions of FERA and found that the amended statute did not apply in this case Pet App at A-52 n 3 The court noted that FERA may also have overruled the requirement of actual payment of a false claim, but found it unnecessary to decide the question because the amended statute was not applicable here Pet. App at A-56-57 n 4

[6] There is a pending Petition for Certiorari for review of the decision in *Duxbury*. Petition for Writ of Certiorari, *Duxbury*, 579 F 3d 13 (No 09-654) (hereinafter Duxbury Pet) On February 22, 2010, the Court invited a response by the Solicitor General As explained below, even if this Court were to grant certiorari in *Duxbury*, there is no basis for holding this case pending review in *Duxbury* *Infra* at 11-14

relaxed for claims under 31 U.S.C. § 3729(a)(2) than for claims under § 3729(a)(1)." Pet. App. at A-58.

Ultimately, the Eleventh Circuit did not decide how specific the allegation of a false claim must be under section (a)(2) because it concluded that the complaint was deficient whether or not it alleged with particularity that a false claim was paid by the government. Pet. App. at A-59. The Eleventh Circuit found the complaint deficient under section (a)(2) because it did not allege, under the applicable pre-amendment language, "that the defendants intended for the government to rely on their false statements in deciding whether to pay a false claim." Pet. App. at A-59, 60. As a result, the Eleventh Circuit concluded that "[w]hether the relators' Complaint alleges with particularity the payment of a false claim is a question we need not answer." Pet. App. at A-59.

REASONS FOR DENYING THE WRIT

I. THE PROCEDURAL OBSTACLES TO REVIEW OF THE QUESTION PRESENTED ARE INSURMOUNTABLE

The procedural posture of this case makes it inappropriate for review by this Court. The first and most obvious obstacle is that the Eleventh Circuit did not address the question on which Petitioners seek review. The Question Presented by Petitioners is: "Whether Rule 9(b), Fed. R. Civ. P. requires the identification of a specific false claim in order to plead a violation of the False Claims Act, 31 U.S.C. § 3729(a)(2)." The Eleventh Circuit did not affirm

dismissal of the section (a)(2) claims based on the complaint's failure to identify a specific false claim. Instead, the court affirmed dismissal because the complaint fails to allege that the defendants *intended* for the government to rely on their false statements in deciding whether to pay a false claim. Pet. App. at A-59.

The barriers to this Court's review are both jurisdictional and prudential. Petitioners, of course, are limited by the question they presented. *Yee v. City of Escondido*, 503 U.S. 519, 535 (1992) (Sup Ct. R. 14.1(a)), which limits this Court's consideration to the questions set forth in the petition or fairly included therein, serves important purposes of notice and conservation of resources). A decision by this Court on the Question Presented by Petitioners would be purely advisory because the decision below turned on other grounds. This Court does not grant certiorari to issue advisory opinions. *See The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959) ("While this Court decides questions of public importance, it decides them in the context of meaningful litigation. Its function in resolving conflicts among the Courts of Appeals is judicial, not simply administrative or managerial. Resolution here of the . . . [issue in conflict among the circuits] can await a day when the issue is posed less abstractly "); *see also* Gressman, et al., *Supreme Court Practice*, ch. 4.4(f) at 248 (9th ed. 2007) (Court does not grant certiorari to review alleged conflict if the issue is irrelevant to the ultimate outcome of the case)

This Court could not reach the question presented by Petitioners without first addressing and rejecting the Eleventh Circuit's actual holding regarding the insufficiency of the allegation of intent. That issue is

not before this Court, and is not presented or fairly included in the Question Presented by Petitioners. Review of that question is therefore barred by Sup. Ct. R. 14.1(a). *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 30-31 (1993) (dismissing writ of certiorari as improvidently granted; in order to reach the merits of the question on which certiorari was granted, Court would have to address preliminary question whether Court of Appeals should have permitted petitioners to intervene, but intervention issue was not fairly included in question presented for review); *Smith v. Butler*, 366 U.S. 161 (1961) (dismissing writ as improvidently granted where it became apparent that the decision below did not turn on the issue on which certiorari was granted).[7]

Finally, even if this Court could overcome the procedural barriers to review of the Question Presented, there is no reason for this Court to do so. This Court would have to address the application of Rule 9(b) to the question whether a relator must specifically identify alleged false claims under section (a)(2) even though the Eleventh Circuit never decided that question. This Court ordinarily does not decide issues

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[7] If Petitioners had sought review of the Eleventh Circuit's actual decision on the insufficiency of the allegation of intent, certiorari would not be appropriate. The court's holding is a fact-bound application of what was a settled legal requirement and now only applies to claims that were pending before the effective date of FERA. *See United States v. Varca*, 896 F.2d 900 (5th Cir.), *cert. denied*, 498 U.S. 878 (1990); *Triangle Improvement Council v. Ritchie*, 402 U.S. 497 (1971), *see also Izumi Seimitsu Kogyo Kabushiki Kaisha*, 510 U.S. at 33 (certiorari inappropriate where resolution bound up in the facts of the case and unlikely to lead to the enunciation of any new principle of law) (citing *Yee v. Escondido*, 503 U.S. at 536 (1992)).

that have not been developed and resolved below. *Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 109 (2001) (dismissing writ as improvidently granted), *NCAA v. Smith*, 525 U.S. 459, 470 (1999); *Roberts v. Galen of Va.*, 525 U.S. 249, 253-54 (1999); *United States v. Bestfoods*, 524 U.S. 51, 72-73 (1998).

Application of that rule is particularly appropriate here. Petitioners claim that there is a circuit split regarding the application of Rule 9(b) to the allegation of a false claim in *qui tam* complaints under section (a)(2) of the FCA and they cite the First Circuit's decision in *Duxbury* as an example of the conflict. Pet. at 20. In fact, the Eleventh Circuit in this case noted that, were it to reach the issue, it might follow the lead of the First Circuit in *Duxbury* and apply a more relaxed standard for the allegation of a false claim under section (a)(2) than for the allegation of a false claim under section (a)(1). Pet. App. at A-58 (citing *Duxbury* and observing that "in the appropriate case, we may consider whether the particularity requirements of Rule 9(b) . . . are more relaxed for claims under 31 U.S.C. § 3729(a)(2) than for claims under § 3729(a)(1)," but declining to address that issue in this case). This Court should not grant certiorari to resolve an alleged conflict where the courts of appeal are themselves considering application of their own precedents in light of the decisions of other circuits. *See McCray v. New York*, 461 U.S. 961, 963 (1983) (Stevens, J.). In addition, before this Court could address whether there should be a relaxed pleading rule for claims brought under section (a)(2) of the FCA, this Court would have to determine whether this issue, which was not addressed by the Eleventh Circuit, was waived by Petitioners in the District Court *See* Resp. App.

at 1a-5a (arguing that Eleventh Circuit should not address the issue because of Petitioners' default); *Abdur'Rahman v. Bell*, 537 U.S 88 (2002) (dismissing certiorari because of possible procedural default).

In sum, there are jurisdictional and prudential reasons not to grant a writ of certiorari in this case and no good reason to grant the writ. This Court repeatedly has determined, both in declining to grant writs of certiorari and in dismissing writs as improvidently granted, that it will not expend its scarce resources to review a case like this, which would involve the Court in a procedural morass, would require the resolution of issues not presented in the Question Presented, and even if the Court could reach the Question Presented, would involve application of legal principles to a factual record without the benefit of the reasoning of the court below. That wisdom is particularly compelling where, as here, the question that is presented was waived below and involves the application of a now-superseded statute.

II. THIS CASE SHOULD NOT BE HELD FOR *DUXBURY*

Petitioners urge that, if the Court does not grant a writ of certiorari to review the decision in this case, it should hold the case pending resolution of the petition in *Duxbury*. There is no basis for such a hold. Even if this Court were to grant certiorari in *Duxbury*, resolution of the question presented in that case would have no impact on this case. *See Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (Court asserts the power to grant, vacate and remand when there is "a reasonable probability that the decision below rests upon a premise that the lower court

would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation"); *see also Wellons v. Hall*, 558 U.S. --, 130 S.Ct. 727 (2010) (Scalia, J. dissenting) (protesting that even the *Lawrence* standard is "flabby").

Petitioners in *Duxbury* present two questions for this Court's review. The first addresses the "public disclosure" bar to a *qui tam* suit under the False Claims Act. *Duxbury* Pet. at (i). Resolution of that question would have no bearing on this case because the Eleventh Circuit did not rule on whether there was a public disclosure. The second question presented in *Duxbury* is "[w]hether an FCA relator, alleging that the defendant induced a third party to submit false or fraudulent claims, can satisfy Rule 9(b) of the Federal Rules of Civil Procedure without identifying a single false or fraudulent claim, but merely by alleging facts sufficient 'to strengthen the inference of fraud beyond possibility.'" *Id.*

Petitioners in this case seek review only of the Eleventh Circuit's determination that their complaint failed to state a claim under section (a)(2) of the FCA. The Eleventh Circuit specifically declined to address whether the complaint sufficiently alleged a false claim under section (a)(2) and instead affirmed dismissal on the failure of the complaint to plead the *intent* required under the then-applicable provisions of the statute. A decision in *Duxbury* will have no impact on the soundness of the Eleventh Circuit's decision on the sufficiency of the allegations of intent

Petitioners' claims under section (a)(1) are not properly before this Court. Even if those claims were properly before this Court, a decision in *Duxbury*

would have no impact on the Eleventh Circuit's dismissal. Petitioners in *Duxbury* challenge the First Circuit's pleading standard as too lenient; they urge this Court to require stricter adherence to Rule 9(b)'s requirement that "the circumstances constituting fraud" be stated with particularity. *Duxbury* Pet. at 33 Even if this Court were to agree that the standard in *Duxbury* is too lenient, that decision would have no impact on this case because Petitioners' complaint is inadequate under the "lenient" *Duxbury* standard.

Petitioners' complaint would have failed under the First Circuit's standard because it is devoid of allegations that satisfy the "who, what, when and where" of the alleged fraudulent scheme to get false claims submitted or approved. For instance, the facts in *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007), were similar to those here: the complaint alleged that the defendants induced doctors to prescribe a drug for off-label uses to their patients. They sought an inference that the doctors wrote prescriptions for off-label uses for their federally insured patients and that false claims were therefore submitted to the government. 507 F.3d at 732. The court in *Rost* found the complaint insufficient because it did not sufficiently establish that false claims were submitted for government payment. *Id.* The court concluded that "Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged. But those practices, while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement." *Id.* at 732.

In *Duxbury*, the First Circuit distinguished *Rost* on the facts. The complaint in *Duxbury* identified the

who, what, when and where of alleged false claims submitted to the government. It alleged kickbacks provided by Biotech that resulted in the submission of false claims by eight healthcare providers in the Western United States. It concluded that "[a]lthough a close call," the complaint satisfied Rule 9(b) because, unlike the complaint in *Rost*, the complaint alleged specific medical providers and the dates and amounts of the false claims filed by those providers with the Medicare program. The complaint identified "as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." 579 F.3d at 30.

Petitioners' complaint alleges no such facts. As the Eleventh Circuit explained, "we are unable to discern from the complaint a specific person or entity that is alleged to have presented a claim of any kind, let alone a false or fraudulent claim." Pet. App. at A-48. Instead, like the complaint in *Rost*, Petitioners' complaint "amply describes illegal practices in which [Solvay] allegedly engaged," but it fails to "establish that false claims were submitted for government payment in a way that satisfies the particularity requirement." *Rost*, 507 F.3d at 732-33. The Eleventh Circuit found the complaint in this case deficient for reasons almost identical to those described in *Rost*: the complaint "offers detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe . . . [but] does not allege the existence of a single actual false claim." Pet. App. at A-48.

CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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May 10, 2010

APPENDIX

APPENDIX

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Case No. 08-15810-A

JAMES HOPPER, COLIN HUTTO
Plaintiffs-Appellants,

v.

SOLVAY PHARMACEUTICALS, INC.,
UNIMED PHARMACEUTICALS, INC N/K/A
UNIMED PHARMACEUTICALS LLC
Defendants-Appellees.

BRIEF OF APPELLEES

ON APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE MIDDLE DISTRICT
OF FLORIDA, TAMPA DIVISION
CASE NO. 8:04-CV-02356-SDM-TGW

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* * *

B. The SAC Remains Deficient Under 31 U.S.C. § 3729(a)(2) Even After *Allison Engine*

Before this appeal, Relators did not argue that the SAC satisfied Rule 9(b) under section (a)(2) of the FCA, which creates liability for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2). Instead, Relators only argued that the SAC satisfied this Circuit's Rule 9(b) pleading strictures under section (a)(1) of the FCA, which creates liability for presenting or causing to be presented a false or fraudulent claim. On this argument the parties joined issue, and on this issue the district court, applying Eleventh Circuit precedent, granted Solvay's motion to dismiss.

Now, for the first time, Relators argue on appeal that, even if their pleading fails under (a)(1), their (a)(2) claim must be allowed to survive because (a)(2) only requires allegations of a false record or statement made to get a claim approved; it does not require any allegation that an actual false claim was presented to the Government for payment. (Relators' Br. – Pgs 25-28) Relators attempt to justify their failure to raise this argument in the district court by noting that *Allison Engine Co. v. United States ex rel. Sanders*, – U.S. –, 128 S. Ct. 2123 (2008) was not decided until after this case had been fully briefed and argued to the Magistrate Judge. This argument should be rejected.

1. This Court Should Not Consider the Allison Engine Argument Raised for the First Time on Appeal

"'[A]n issue not raised in the district court and raised for the first time in an appeal will not be considered by this court.'" *Access Now*, 385 F.3d at 1331 (quoting *Walker v. Jones*, 10 F.3d 1569, 1572 (11th Cir. 1994)) Relators seek to justify their failure to have raised their Allison Engine argument below because it was decided "[a]fter briefing and argument to the Magistrate Judge, but before his report and recommendation." (Relators' Br. – Pg 25) Relators urge this Court to consider this new argument because "Supreme Court decisions apply retroactively and prospectively to all cases on direct appeal whenever applied to the litigants before the Court . . . [such that] Appellate courts have the discretion to resolve a question for the first time on appeal, especially if the issue is legal in nature and failure to consider it would result in a miscarriage of justice." (*Id.* – Pg 25 n.8) This Court should not consider this new argument because Relators have waived any right to raise it on appeal.

Certainly, justice would not miscarry for this Court's refusal to consider this newly-raised argument here. Relators had ample opportunity to address *Allison Engine* in the district court. *Allison Engine* was decided on June 9, 2008, nearly two months before the Magistrate Judge issued his R&R (Doc 101), and three months before the district court adopted that R&R and granted Solvay's motion to dismiss. (Doc 106) Yet, Relators never once filed supplemental authority or sought supplemental argument before the various rulings. Nor did they seek reconsideration after them.

Moreover, nearly seven months before the Magistrate Judge issued the R&R on August 1, 2008, counsel for Relators in this case filed an *amicus curiae* brief for Senator Charles Grassley on January 22, 2008 in the very *Allison Engine* case Relators seek to argue for the first time here. *See* Brief of Senator Charles Grassley as *Amicus Curiae* in Support of Respondents, No. 07-214, 2008 WL 205086 (U.S. Jan. 22, 2008). Indeed, Relators' counsel himself made this precise argument just six months before Solvay even filed its motion to dismiss the SAC in *United States ex rel. Howard v. Lockheed Martin*, 499 F. Supp. 2d 972 (S.D Ohio 2007).[1] In *Howard*, Relators' counsel "argue[d] that they [were] not required under the FCA to plead the actual presentment of claims based on a recent Sixth Circuit precedent." *Id.* at 976. The "recent Sixth Circuit precedent" to which Howard cited was none other than *United States ex rel. Thacker v. Allison Engine Co., Inc.*, 471 F.3d 610 (6th Cir. 2006).

As this Court has noted, "'[t]oo often our colleagues on the district court complain that the appellate cases about which they read were not the cases argued before them.'" *Access Now*, 385 F.3d at 1331 (quoting *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998)). Certainly, the district court here would share a similar sentiment if this Court considered this new argument now. The retroactivity of *Allison Engine* is irrelevant given the ample opportunity Relators had to raise it in the district court. *See, e.g., Deffenbaugh-Williams v. WalMart Stores*, 188 F.3d 278, 282 (5th Cir. 1999) (even when the law changes while a case is pending appeal, remand is

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[1] *Howard* was decided on June 28, 2007, and Solvay filed its Motion to Dismiss on December 28, 2007 (Doc 88)

not appropriate where the case law is "within the reach of an informed attorney.").